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Zeng

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(54) **CATHETER PUMP ASSEMBLY INCLUDING A STATOR**

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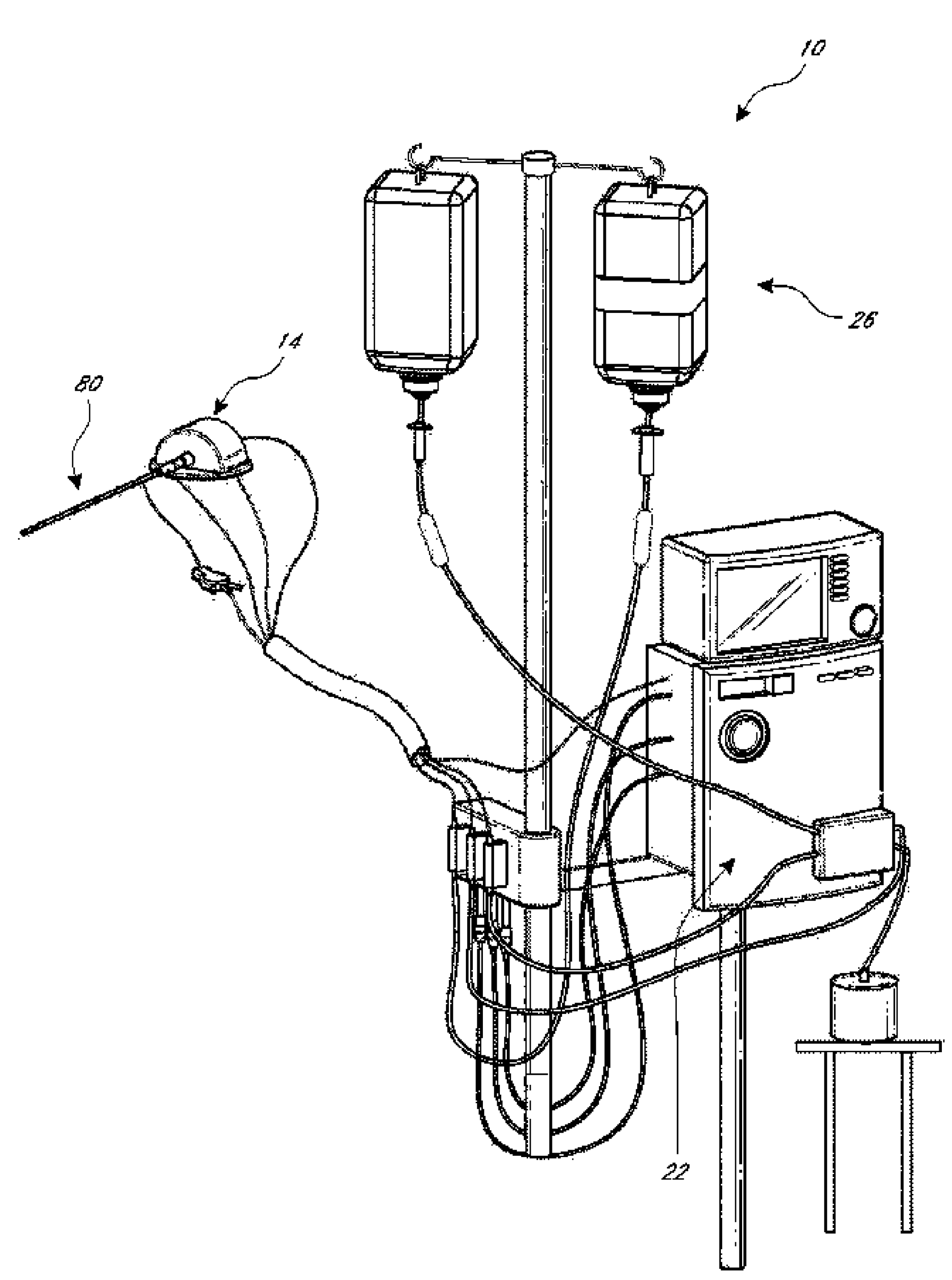
(57) **ABSTRACT**

A catheter pump assembly is provided that includes a proximal a distal portion, a catheter body, an impeller, and a flow modifying structure. The catheter body has a lumen that extends along a longitudinal axis between the proximal and distal portions. The impeller is disposed at the distal portion. The impeller includes a blade with a trailing edge. The flow modifying structure is disposed downstream of the impeller. The flow modifying structure has a plurality of blades having a leading edge substantially parallel to and in close proximity to the trailing edge of the blade of the impeller and an expanse extending downstream from the leading edge. In some embodiments, the expanse has a first region with higher curvature and a second region with lower curvature. The first region is between the leading edge and the second region.

20 Claims, 26 Drawing Sheets



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continuation of application No. 15/065,573, filed on Mar. 9, 2016, now abandoned, which is a continuation of application No. 14/209,889, filed on Mar. 13, 2014, now Pat. No. 9,308,302.

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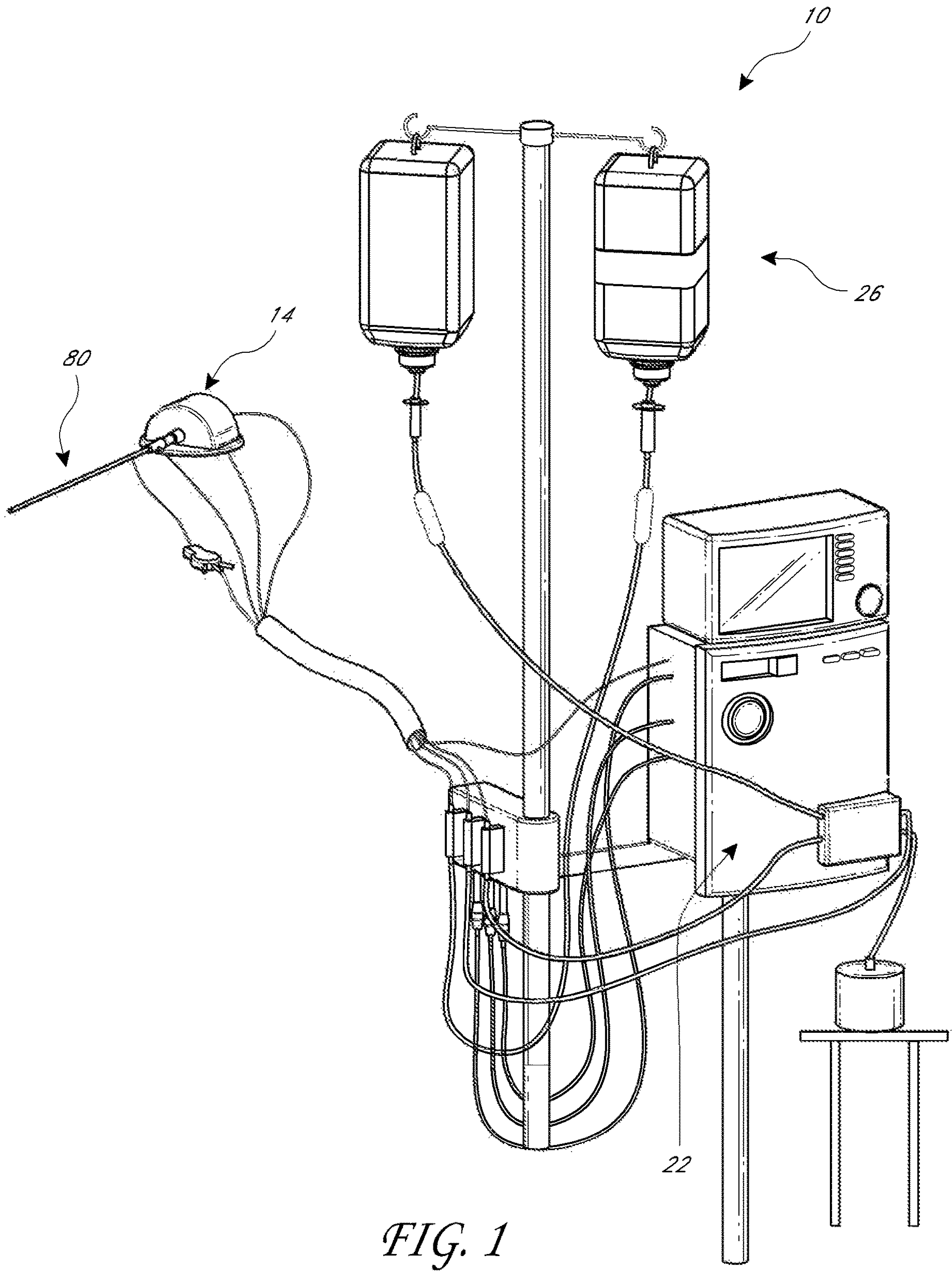

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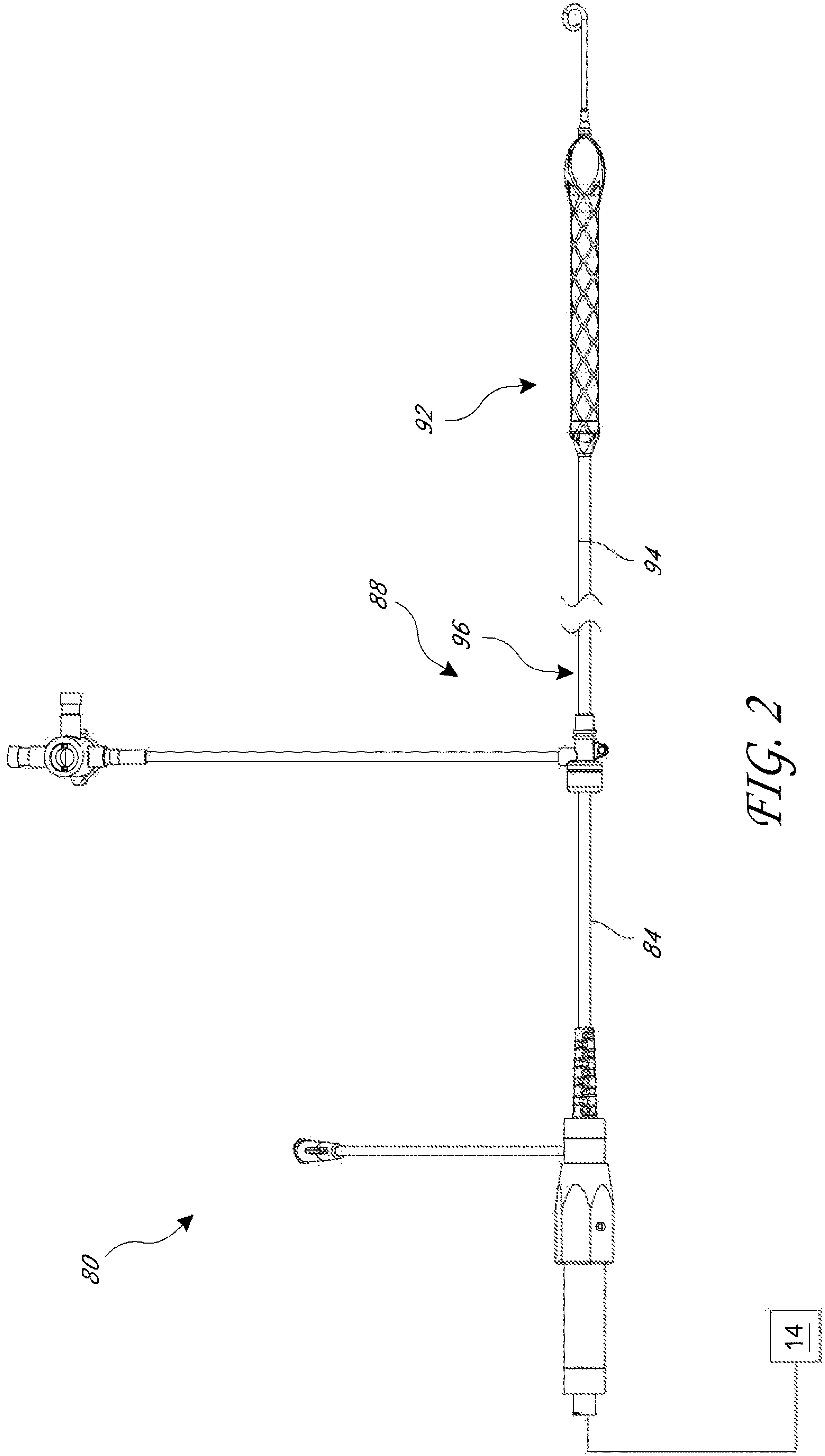

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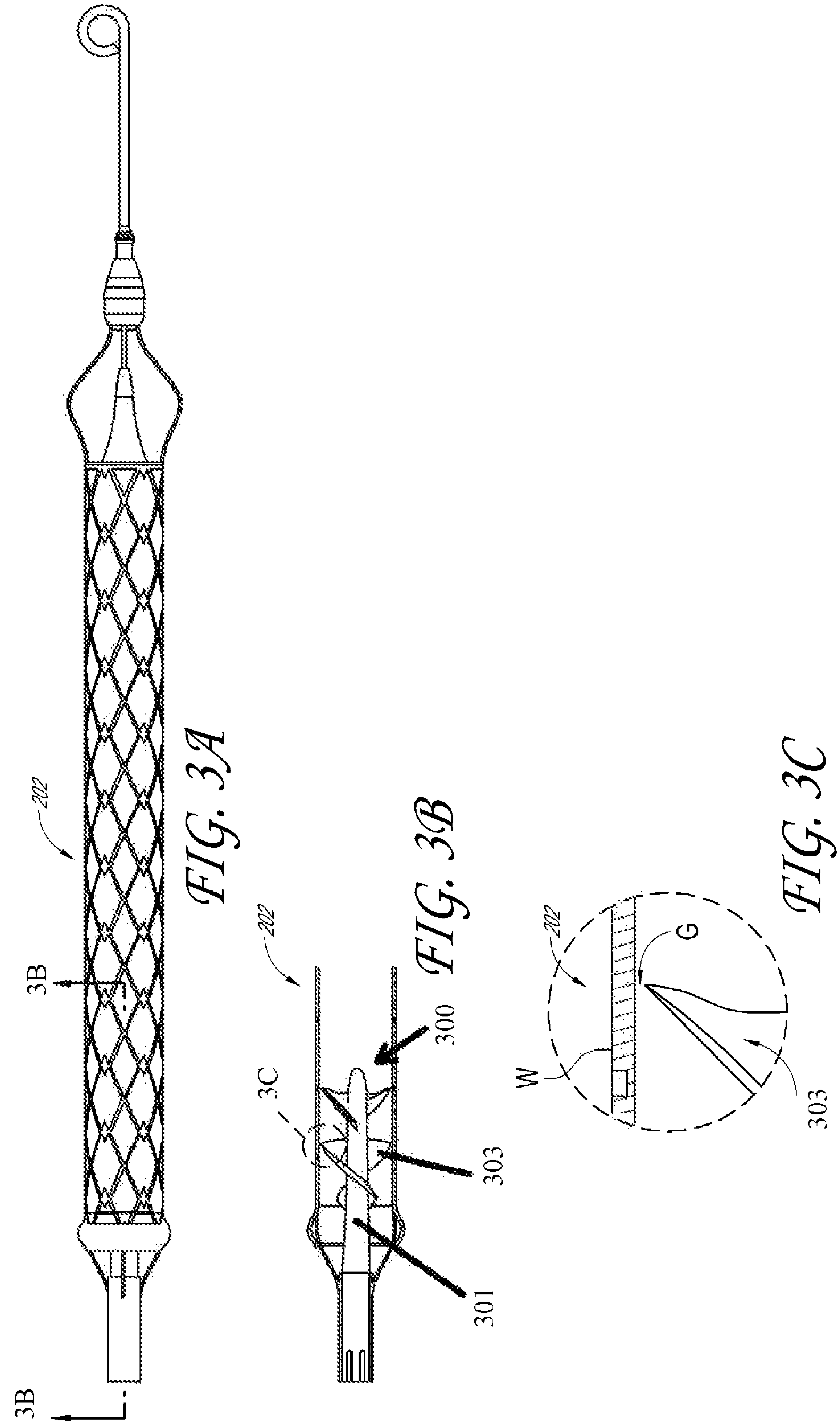
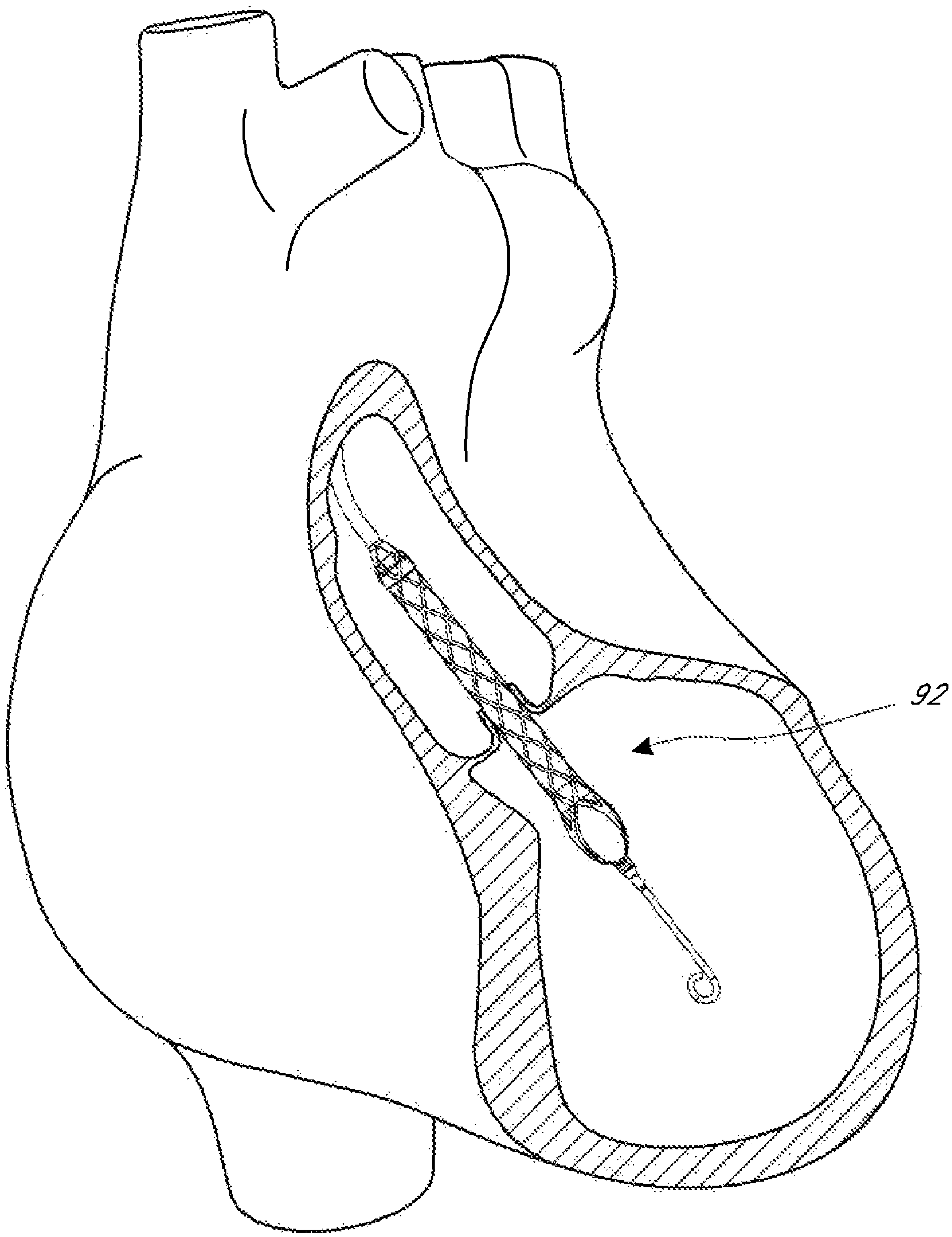


FIG. 3A

FIG. 3B

FIG. 3C



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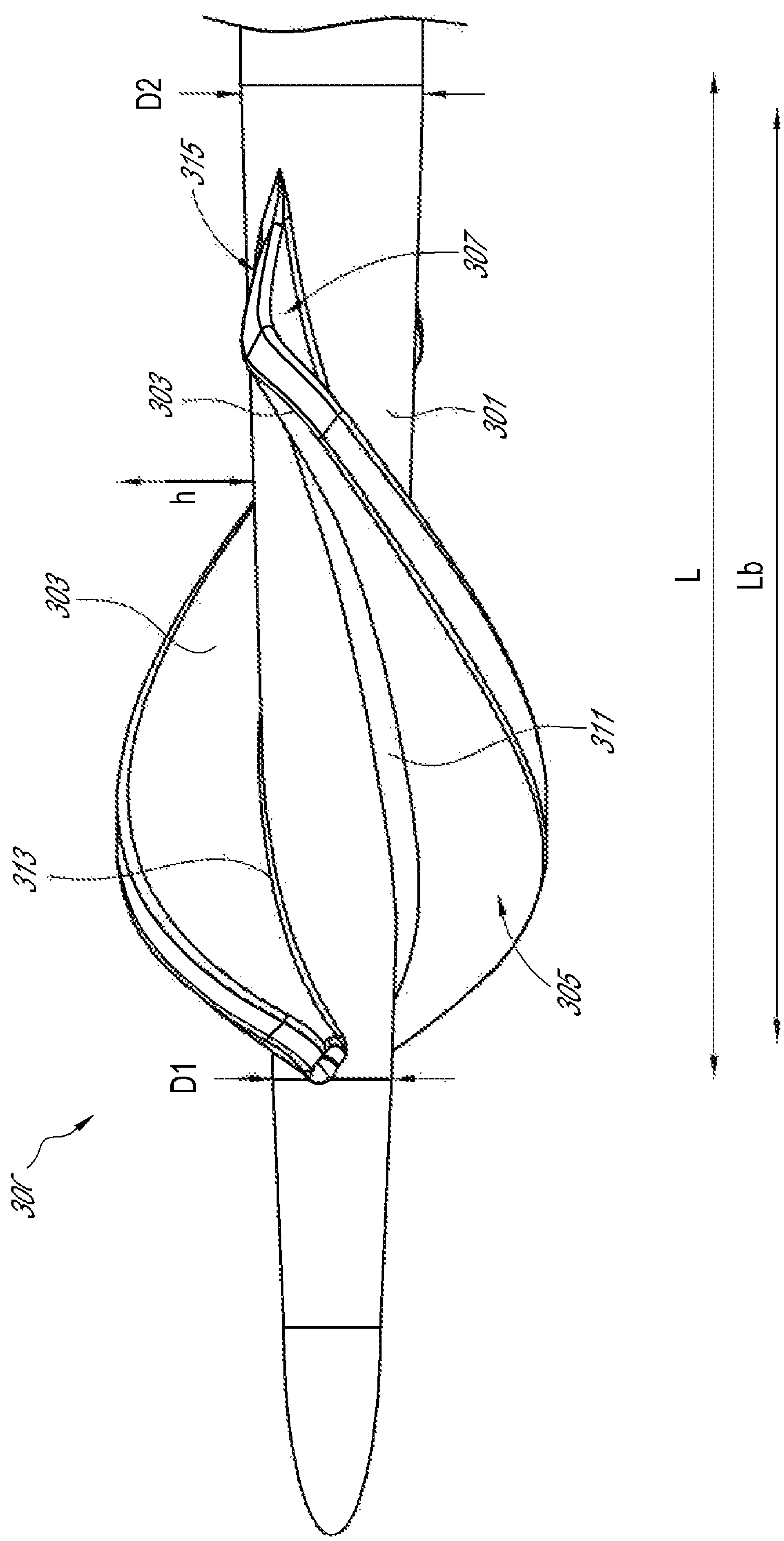


FIG. 5A

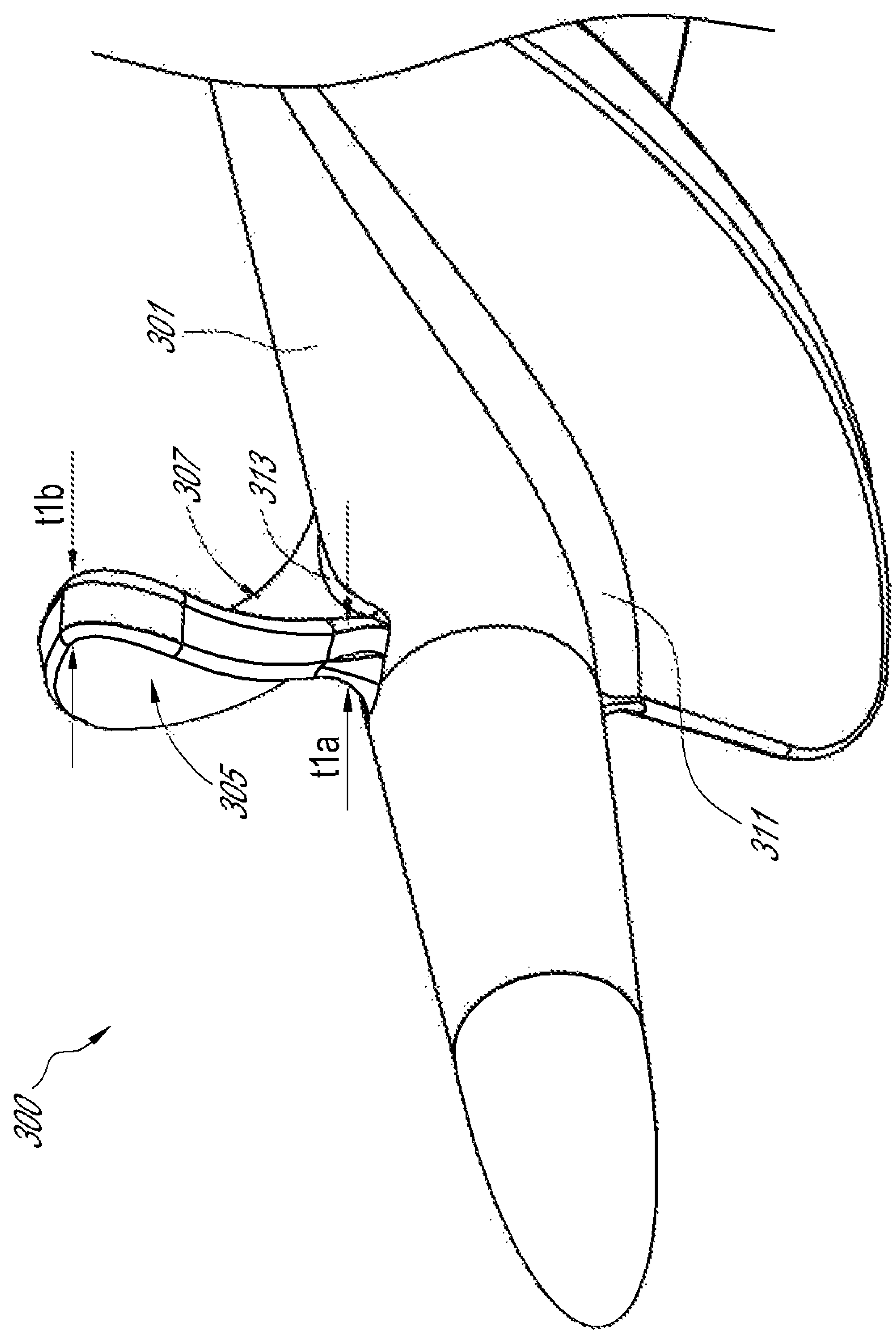


FIG. 5B

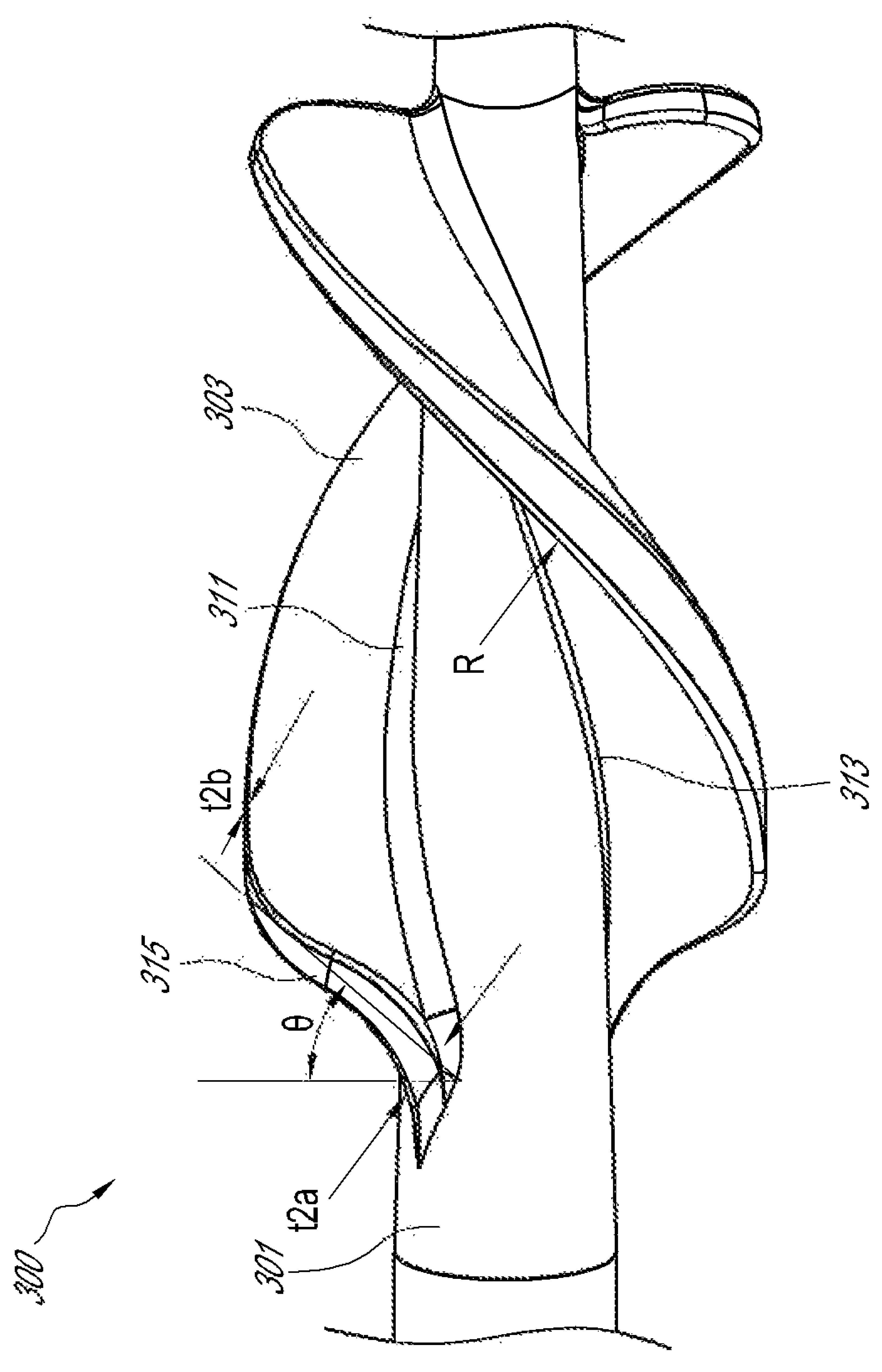


FIG. 5C

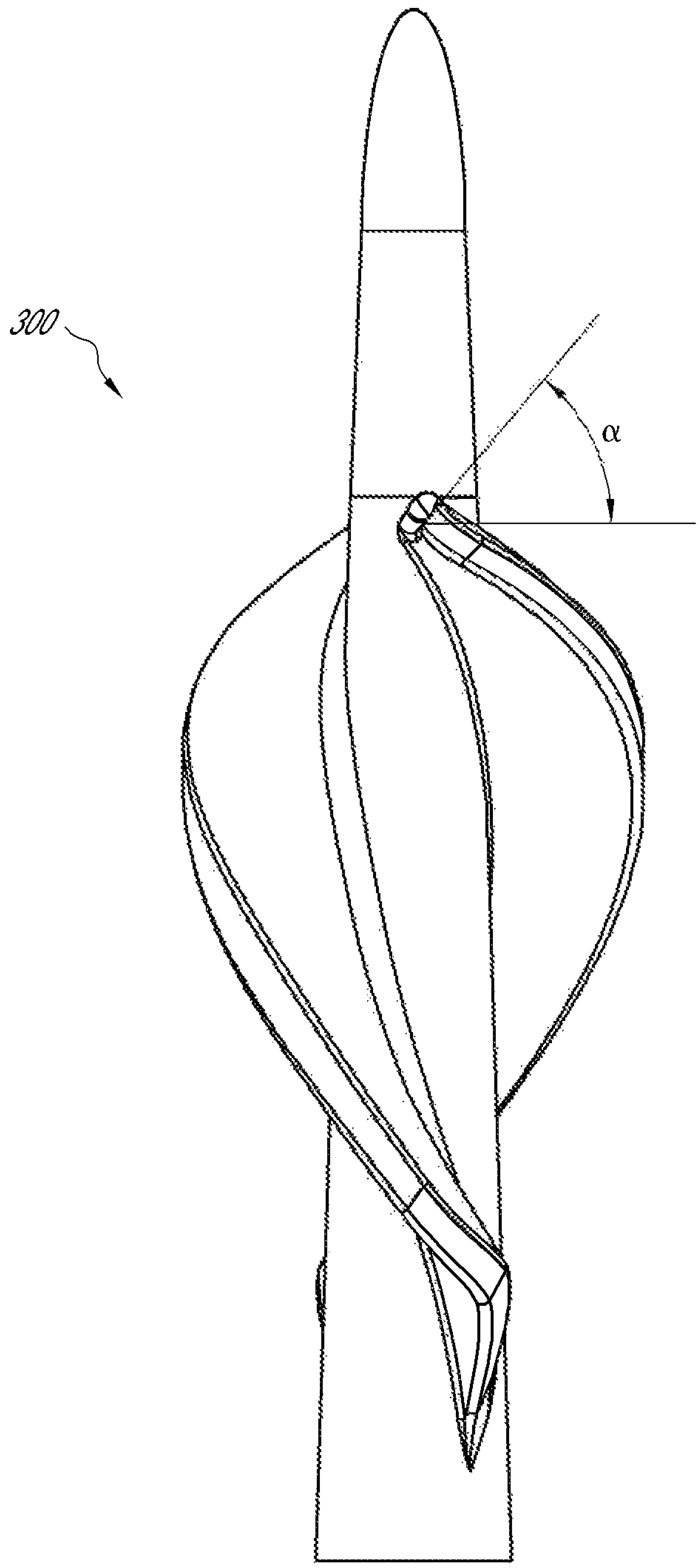


FIG. 5D

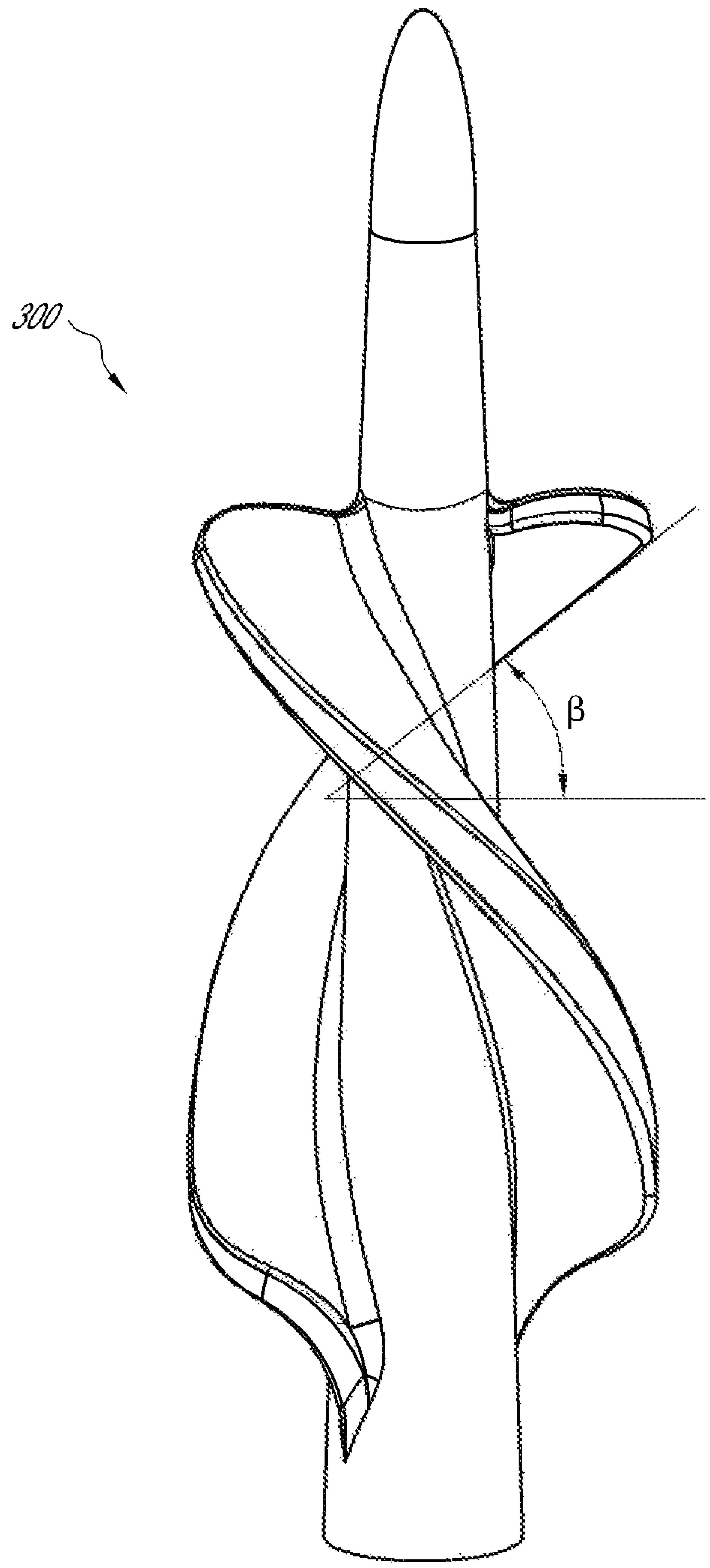


FIG. 5E

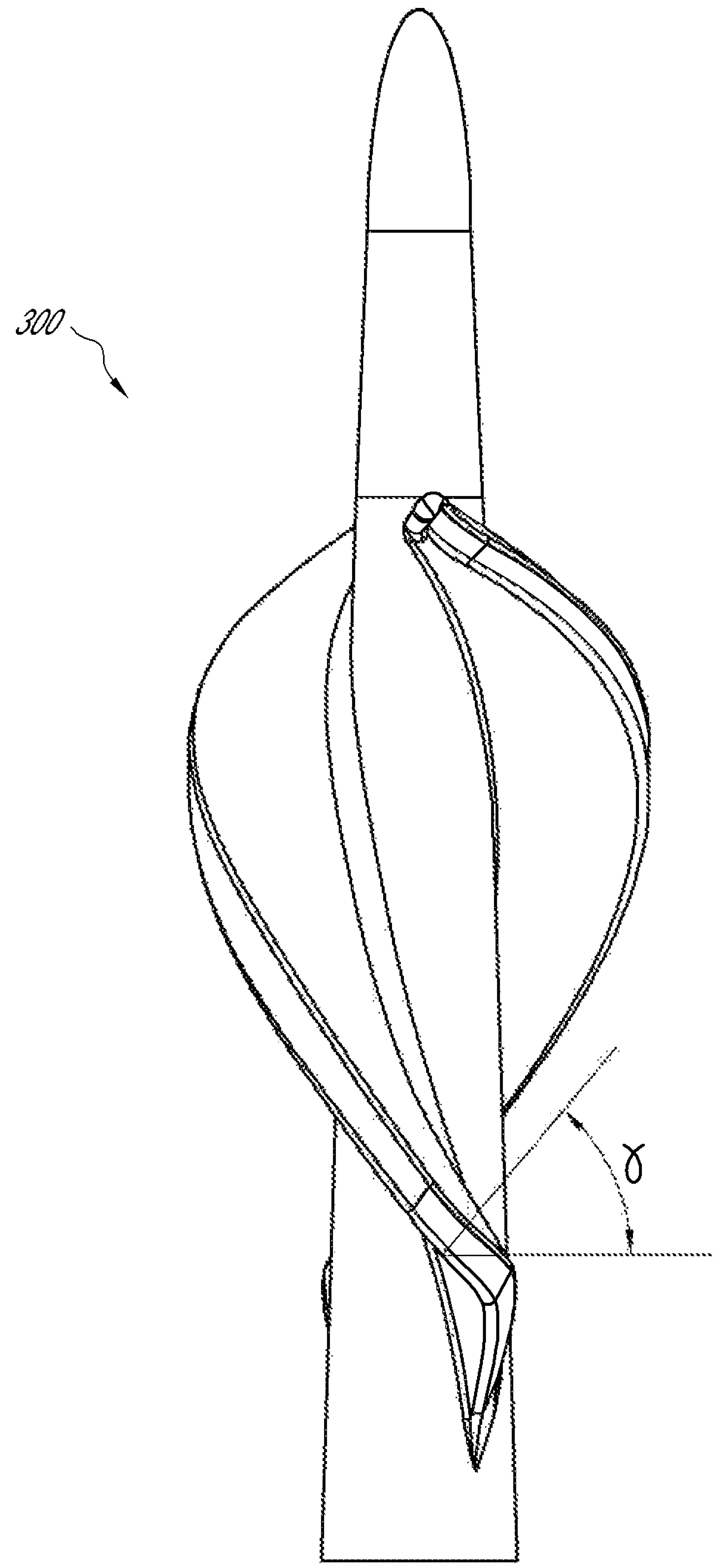
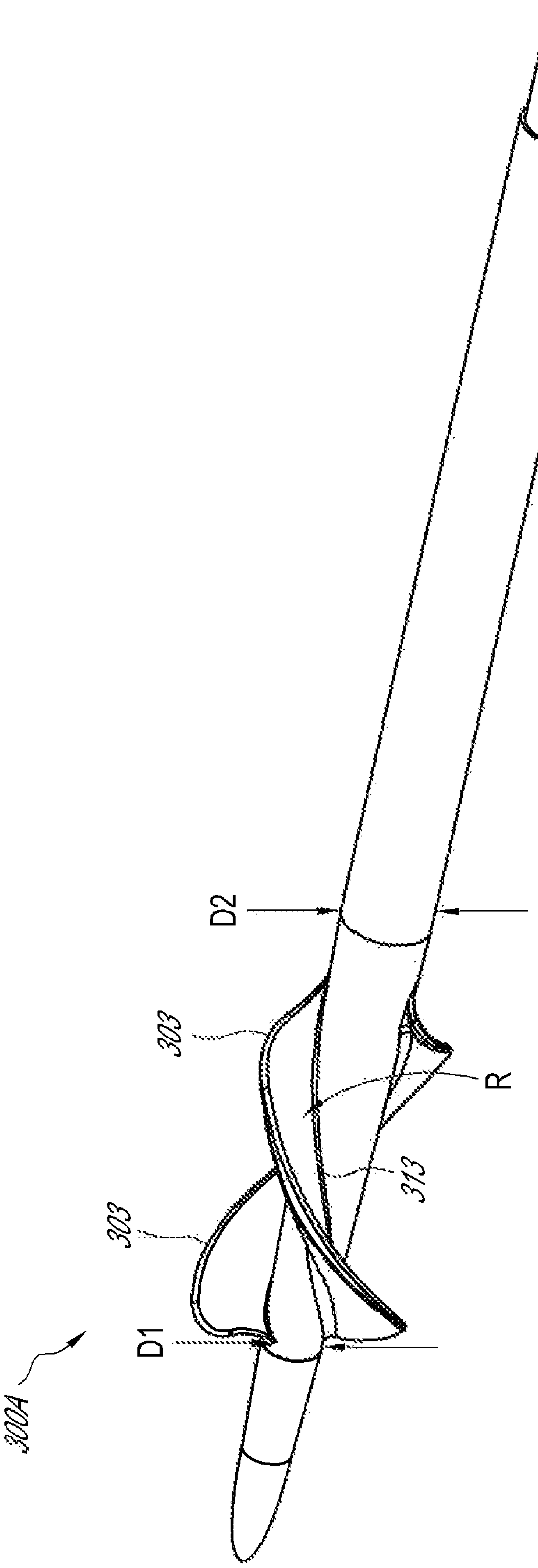


FIG. 5F



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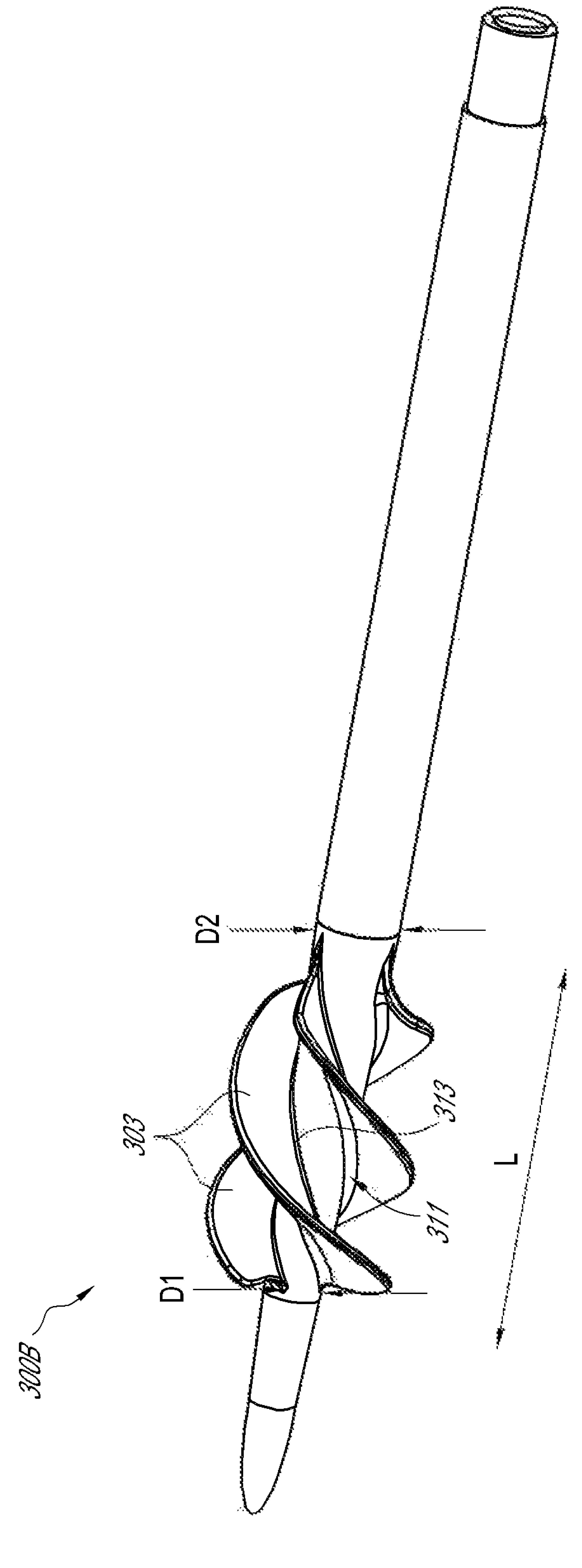

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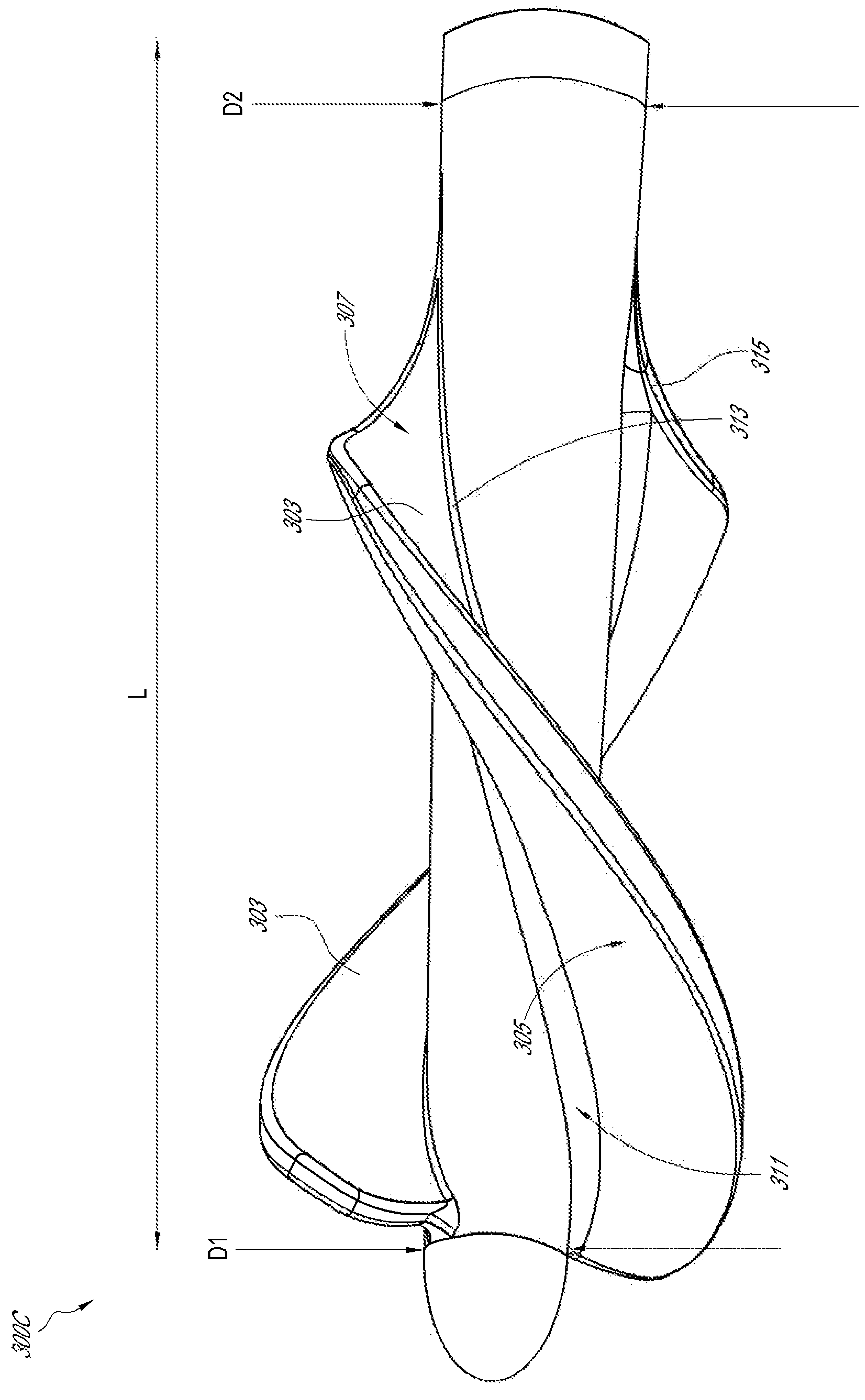

FIG. 8

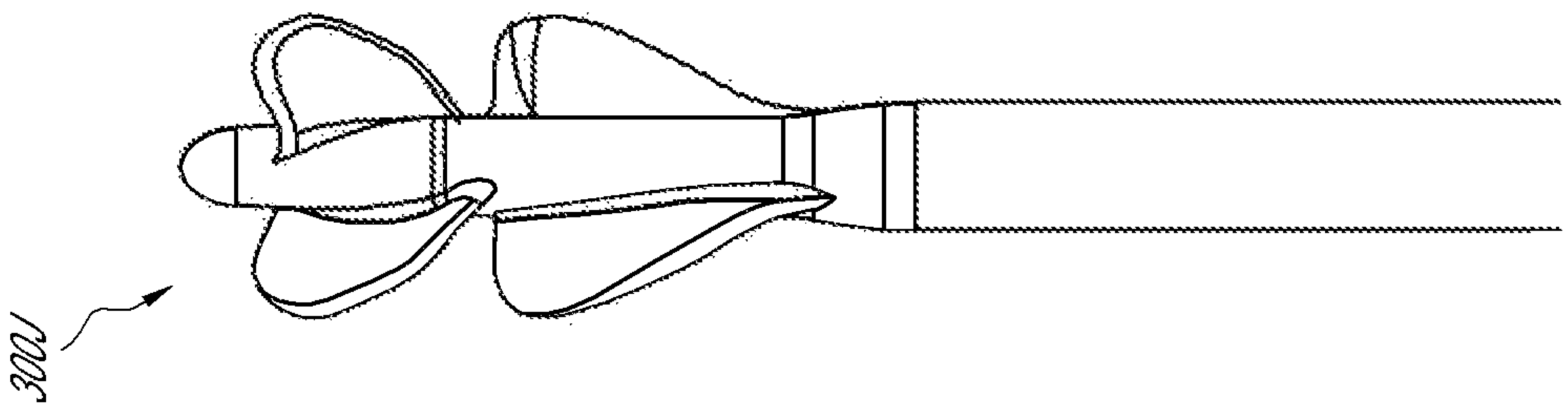

FIG. 9E

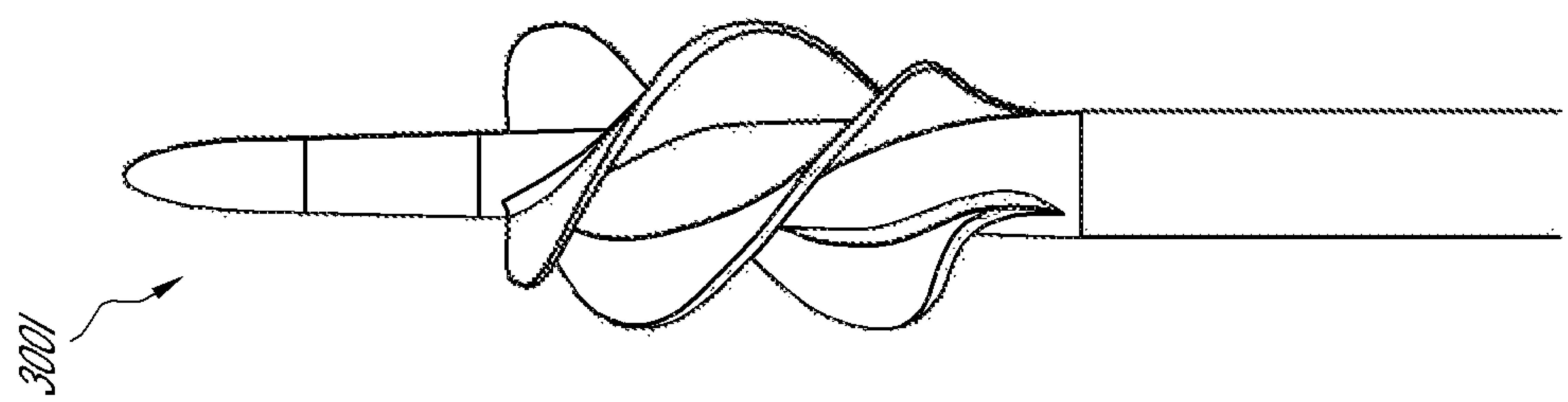

FIG. 9D

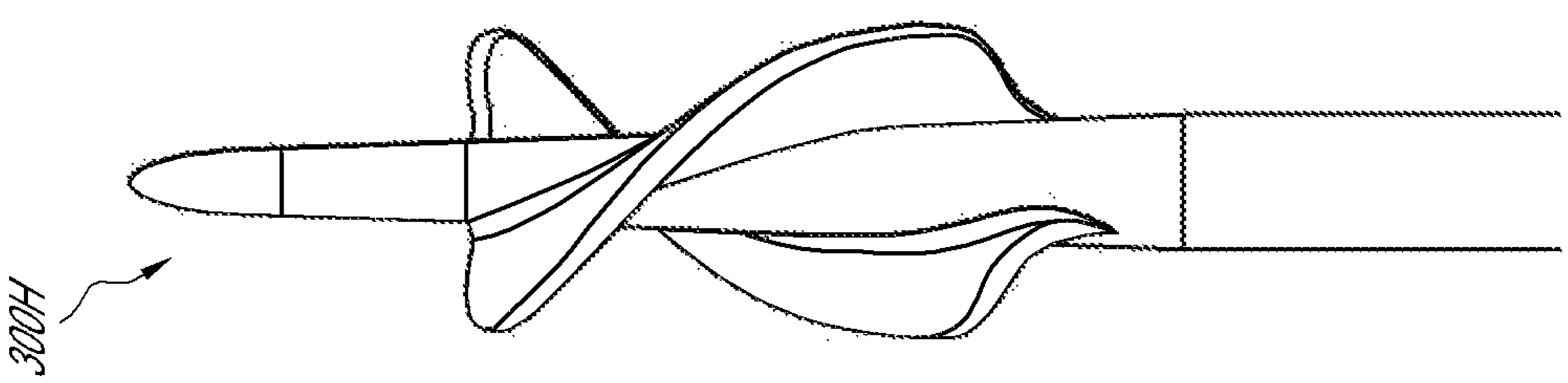

FIG. 9C

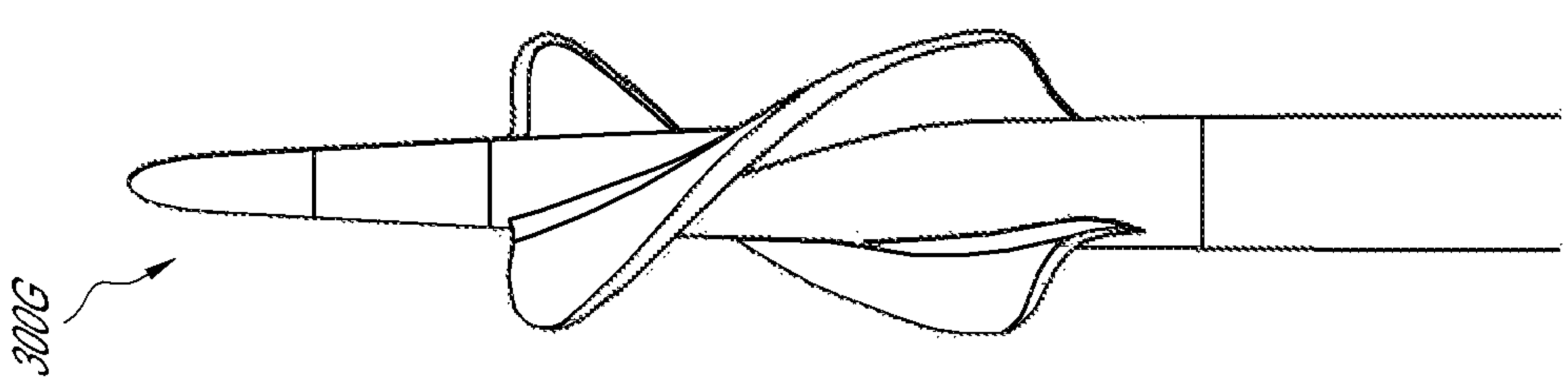

FIG. 9B

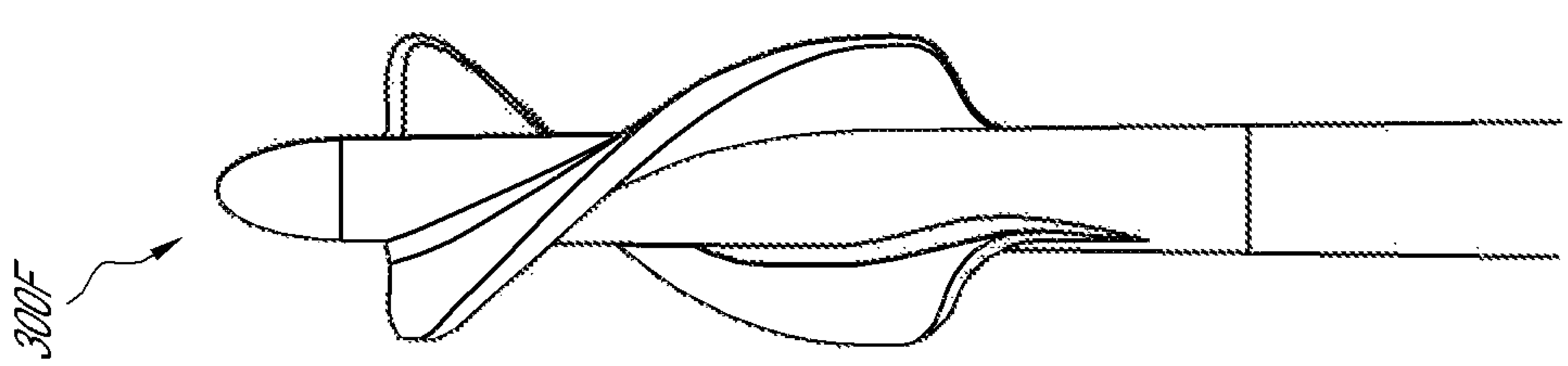

FIG. 9A

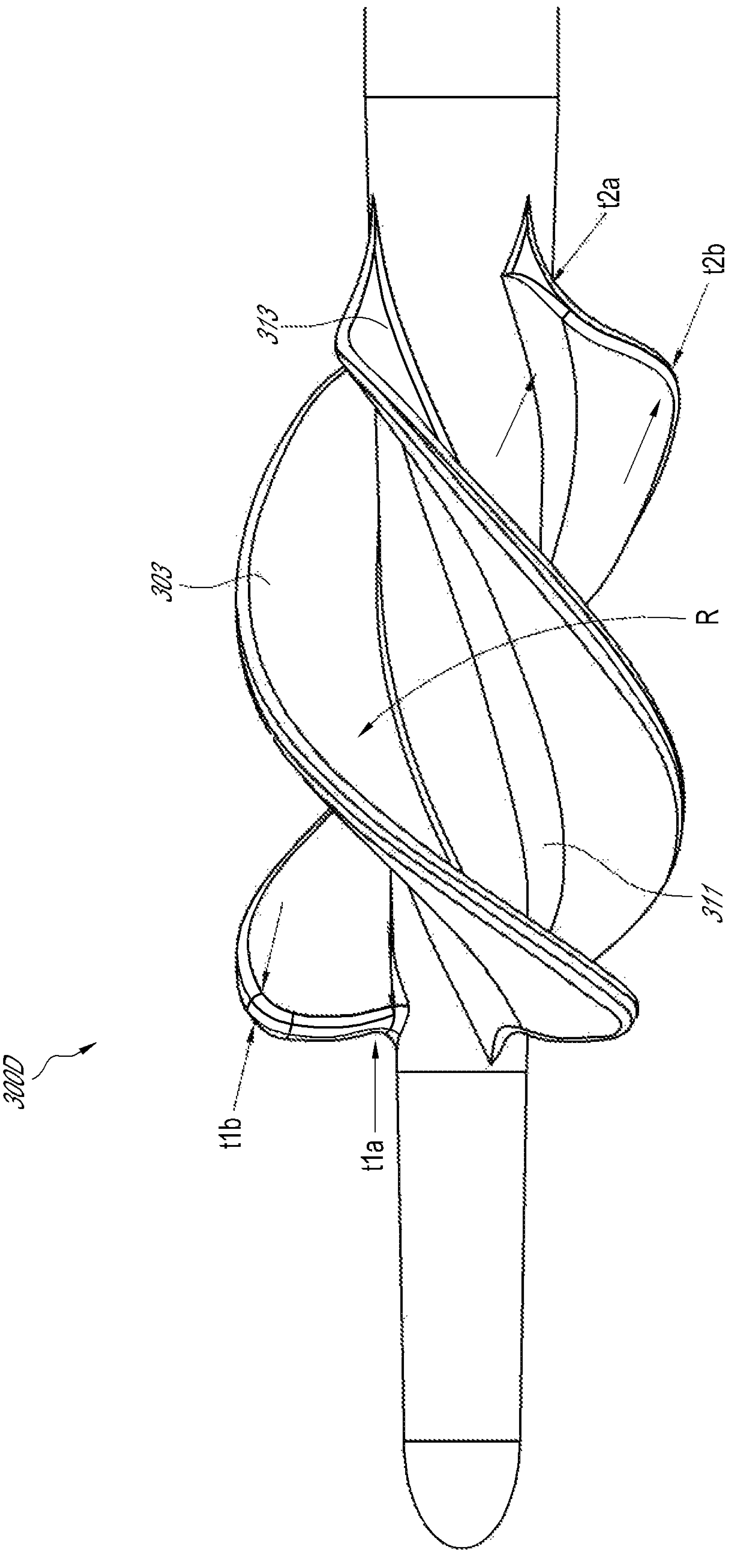

FIG. 10A

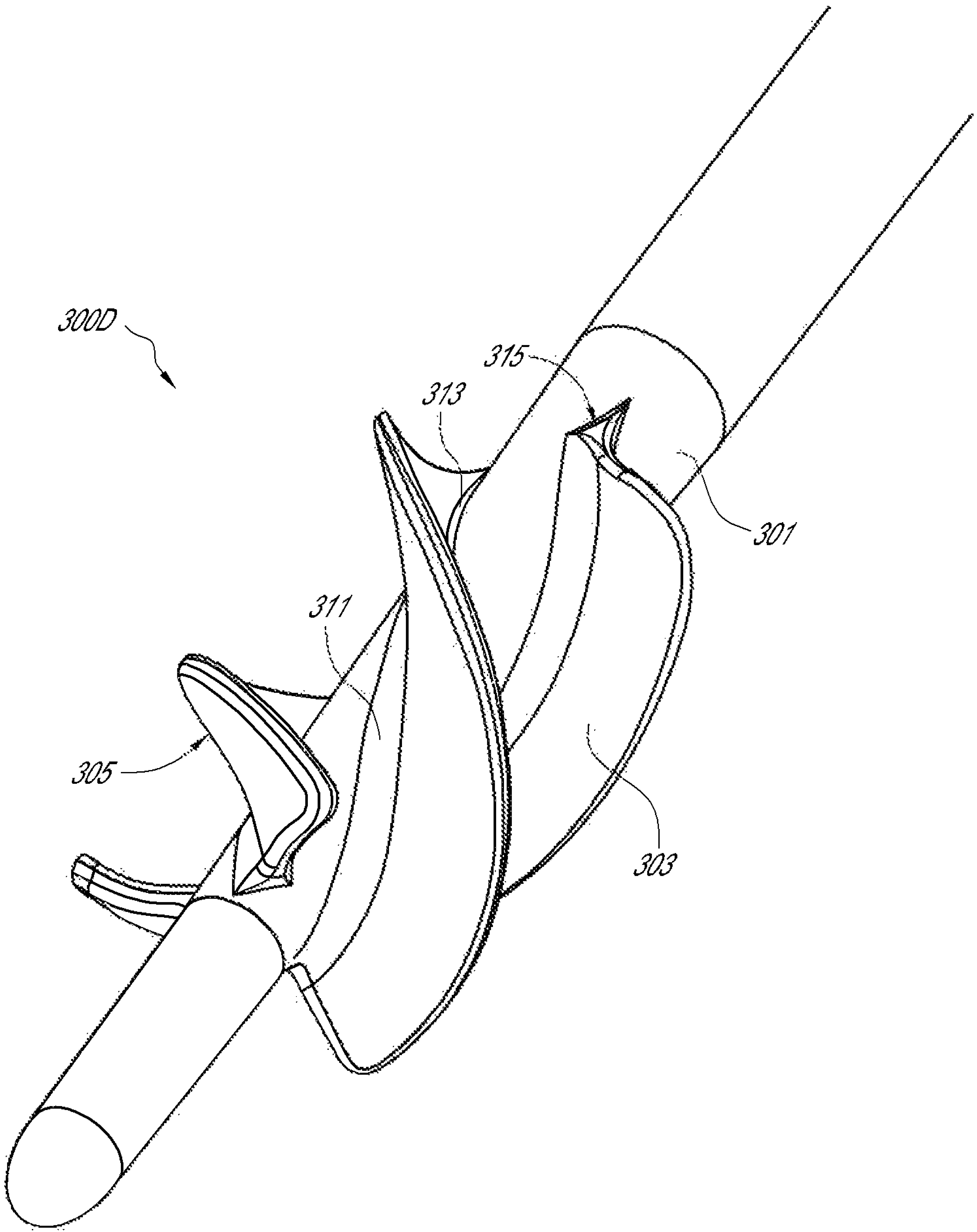

FIG. 10B

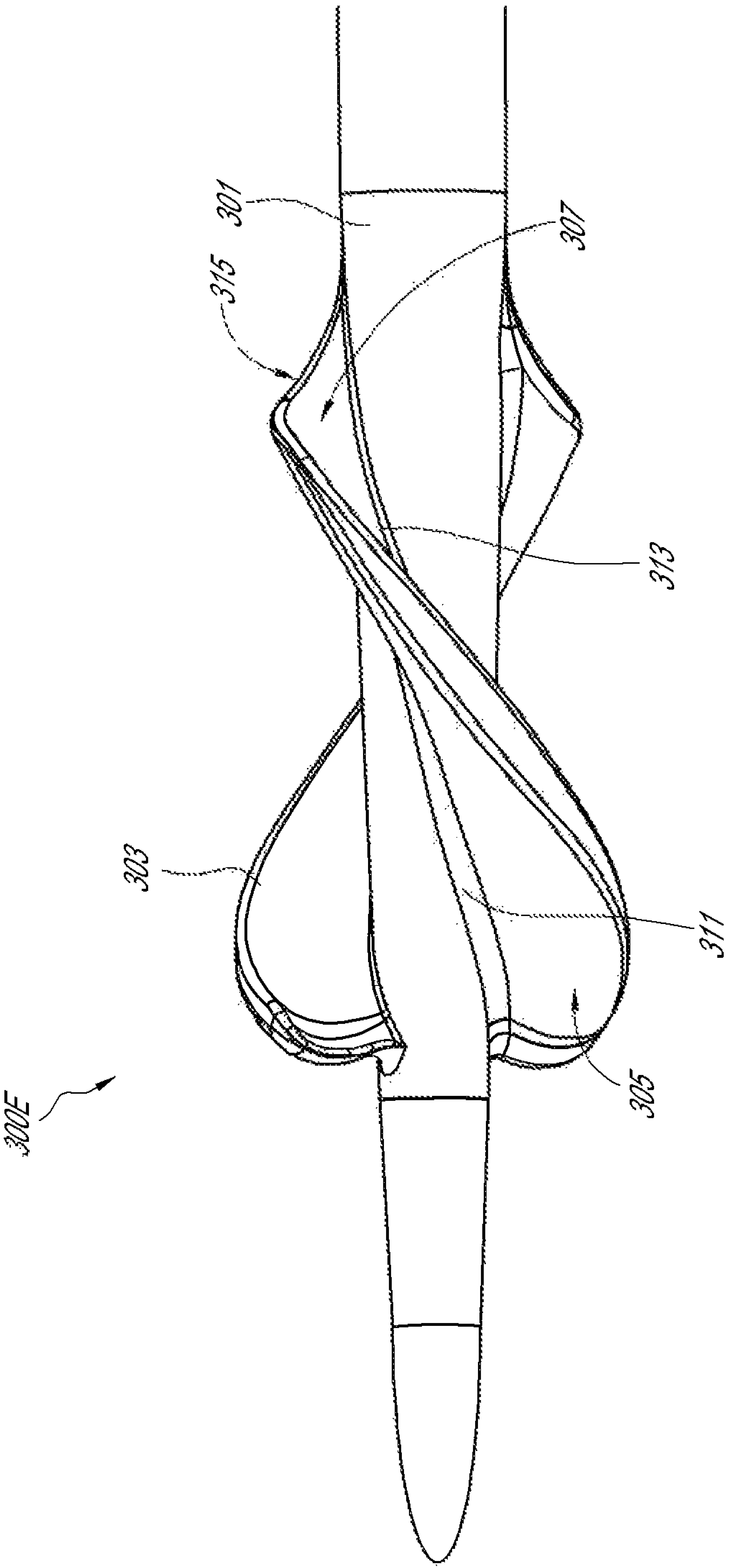

FIG. 11

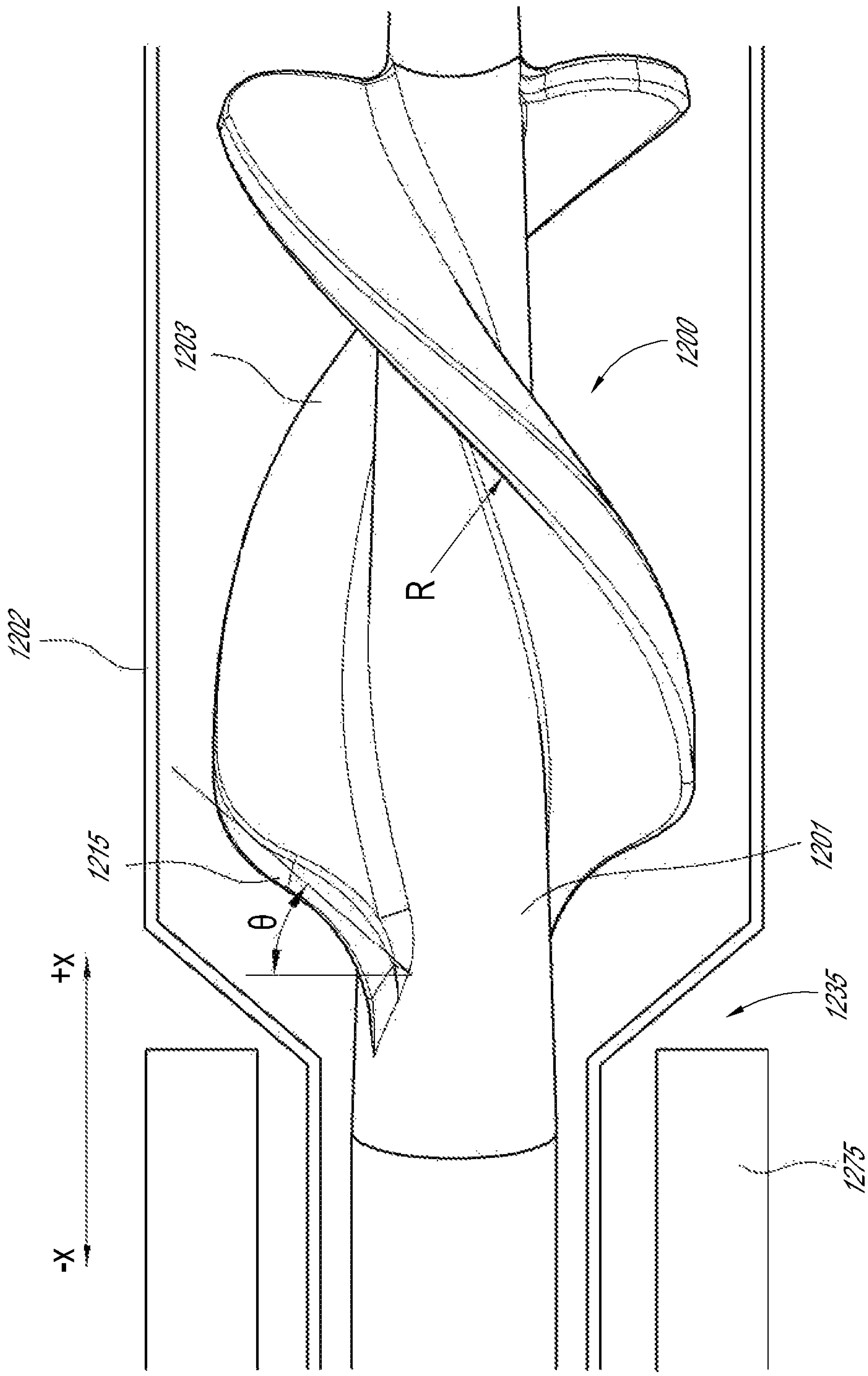

FIG. 12

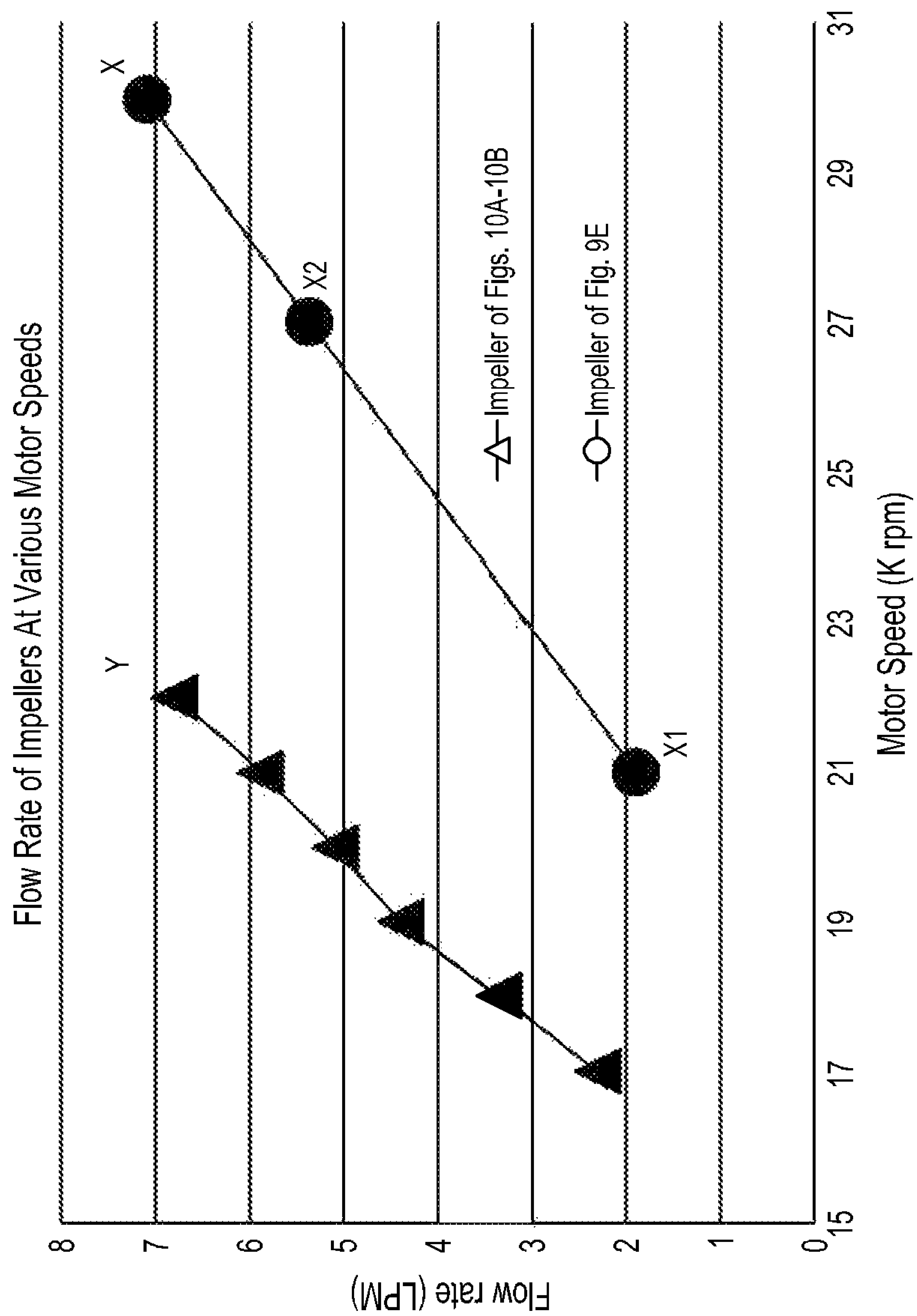
Flow Rate of Impellers At Various Motor Speeds
Flow rate (LPM)
Motor Speed (K rpm)
Impeller of Figs. 10A-10B
Impeller of Fig. 9E
X
X1
X2
Y
0
1
2
3
4
5
6
7
8
15
17
19
21
23
25
27
29
31

FIG. 13

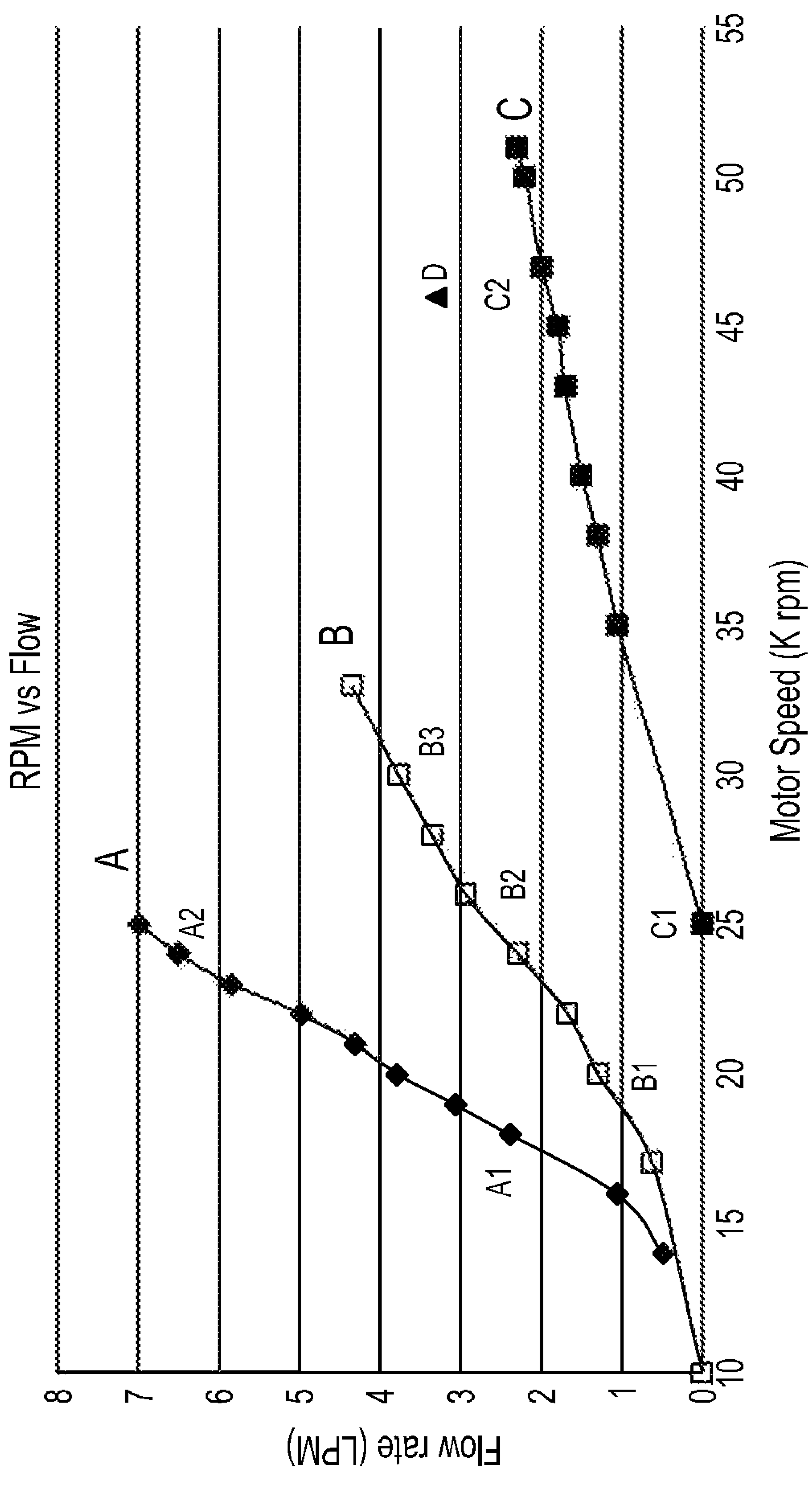
RPM vs Flow
Flow rate (LPM)
0
1
2
3
4
5
6
7
8
Motor Speed (K rpm)
10
15
20
25
30
35
40
45
50
55
A
A1
A2
B
B1
B2
B3
C
C1
C2
D

FIG. 14

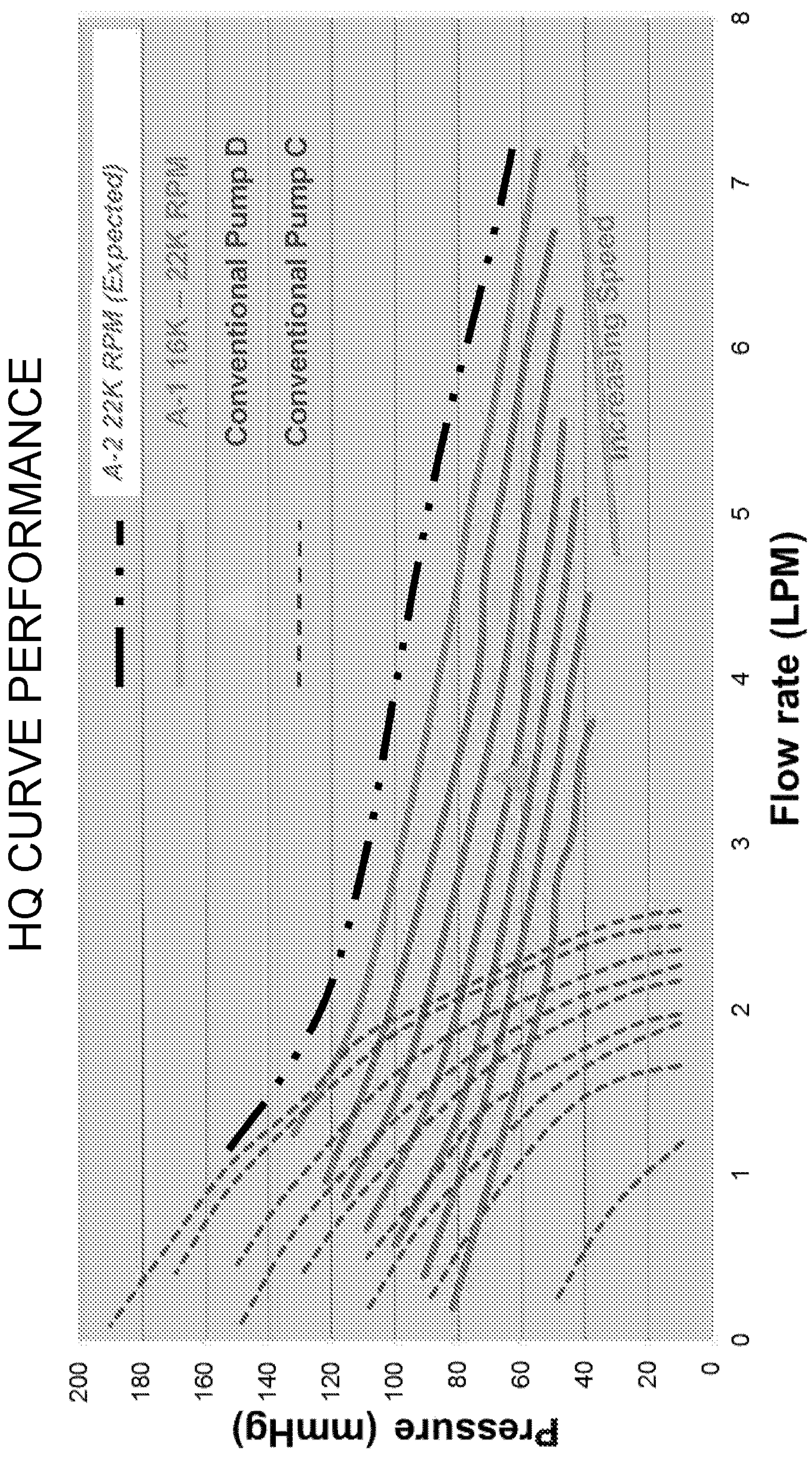
HQ CURVE PERFORMANCE
A-2 22K RPM (Expected)
A-1 16K – 22K RPM
Conventional Pump D
Conventional Pump C
Increasing Speed
Pressure (mmHg)
200
180
160
140
120
100
80
60
40
20
0
0
1
2
3
4
5
6
7
8
Flow rate (LPM)

FIGURE 14A

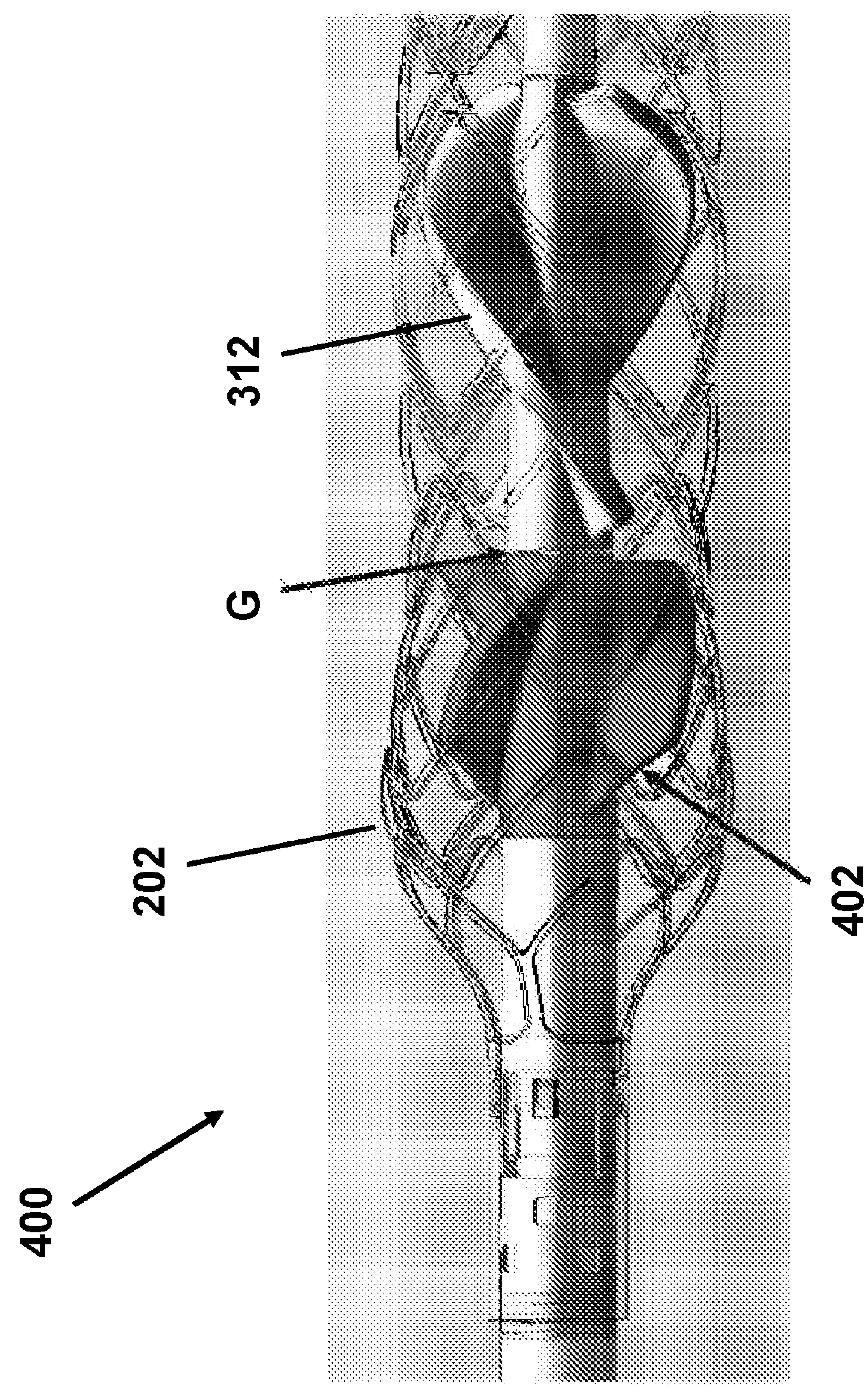

FIGURE 15

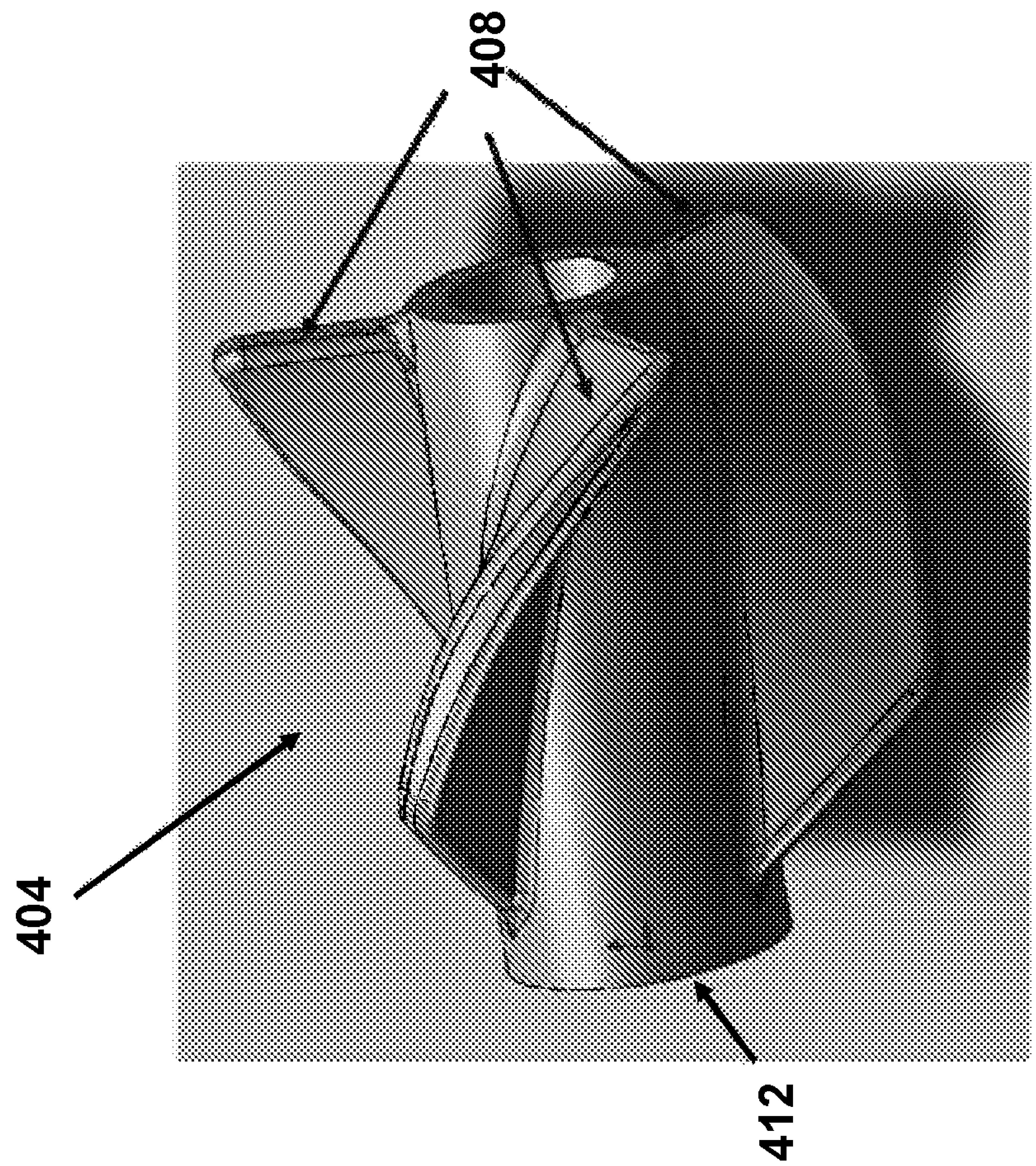

FIGURE 16

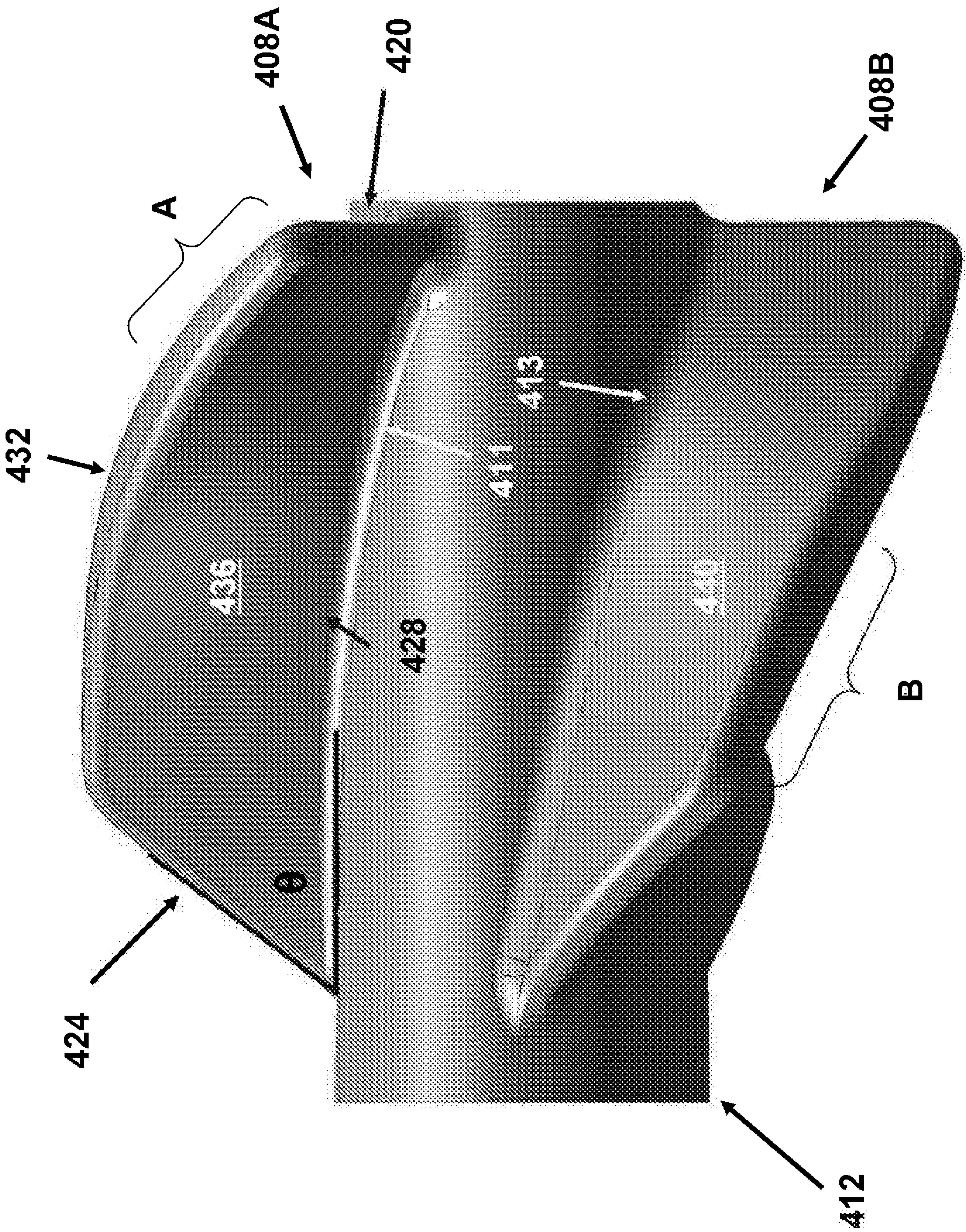

FIGURE 17

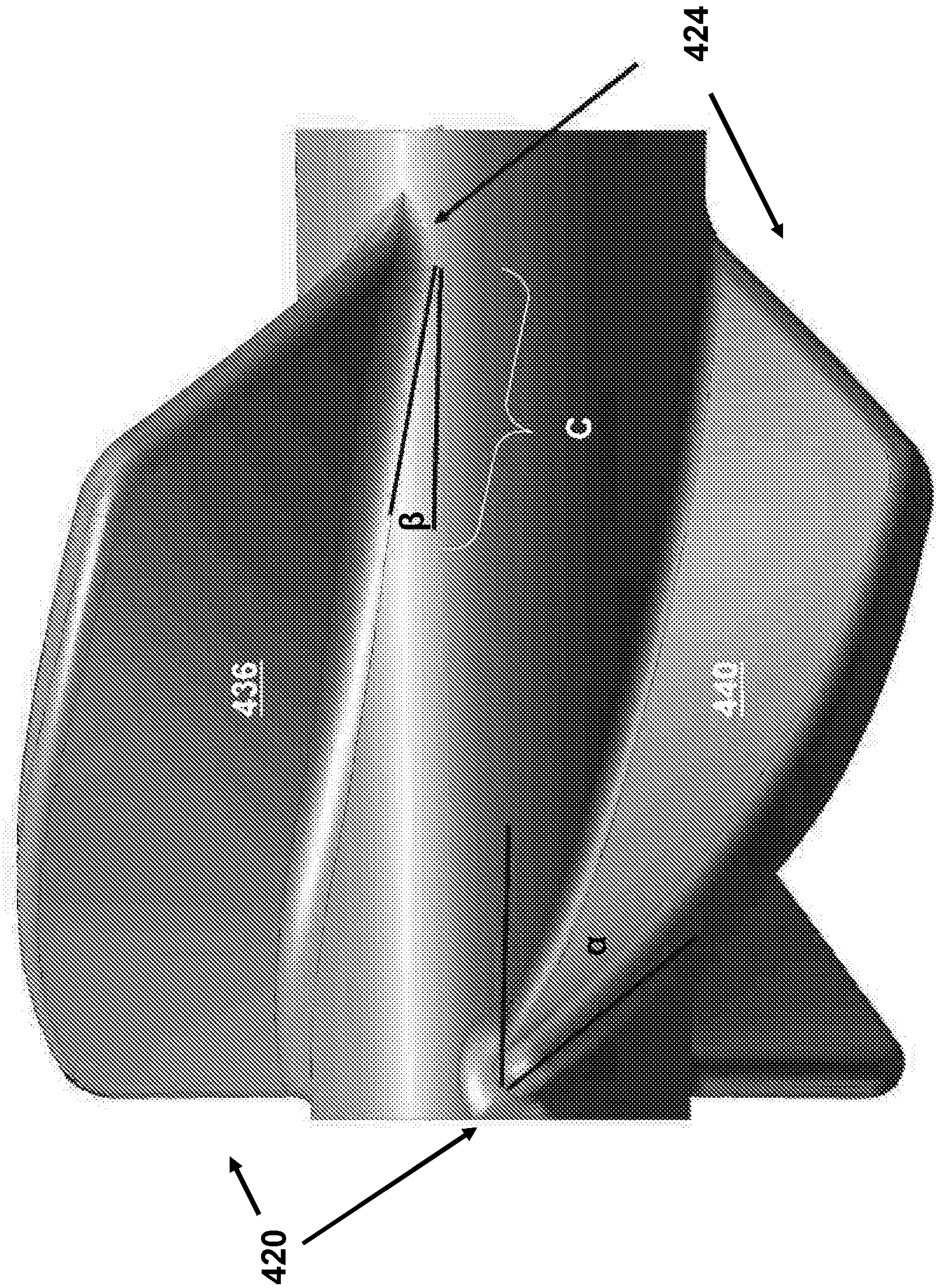

FIGURE 18

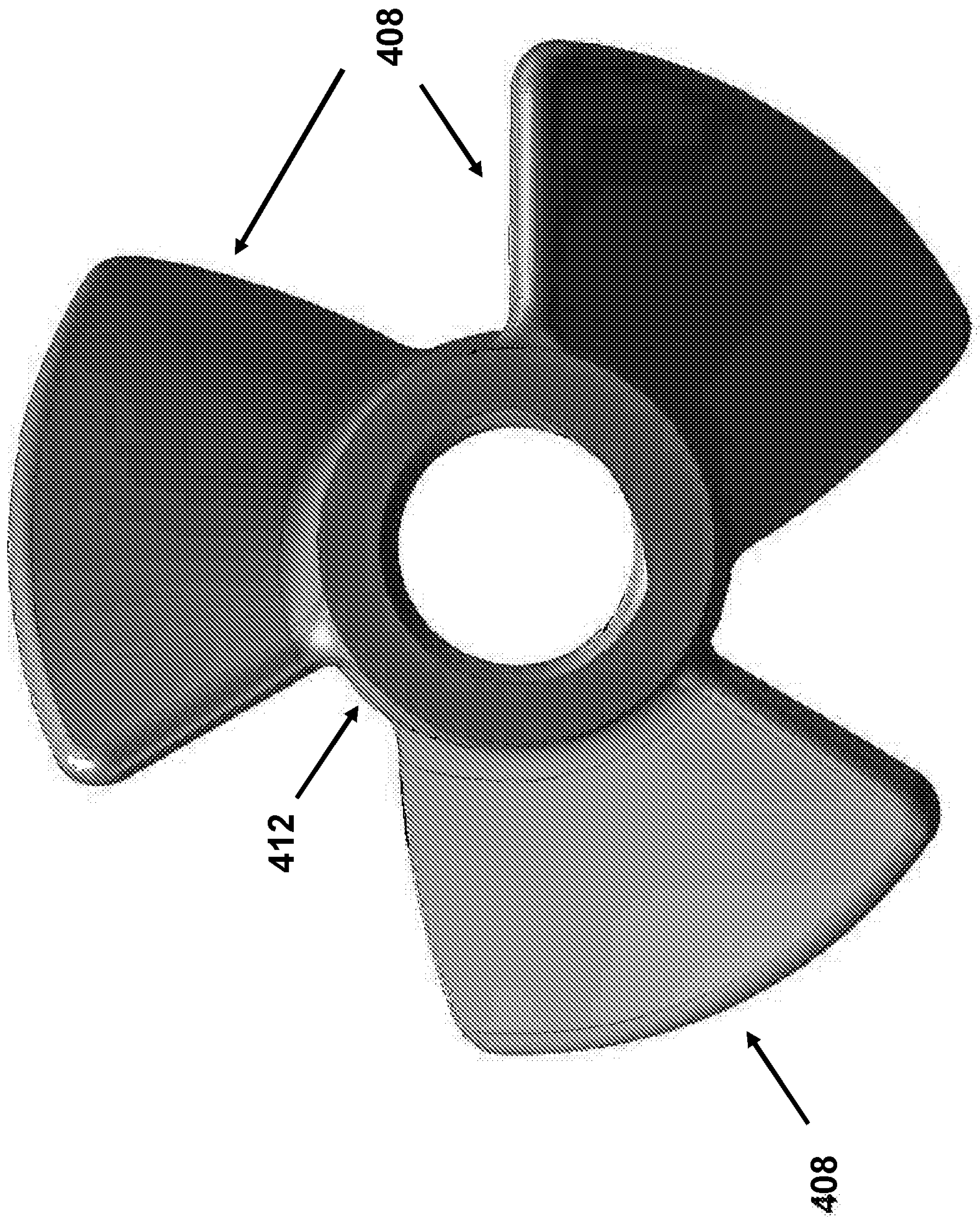

FIGURE 19

CATHETER PUMP ASSEMBLY INCLUDING A STATOR

CROSS-REFERENCE TO RELATED APPLICATIONS

The present application is a Continuation of U.S. patent application Ser. No. 15/458,279, filed on Mar. 14, 2017, and issued as U.S. Pat. No. 10,071,192, which is a Divisional of U.S. patent application Ser. No. 15/065,573, filed on Mar. 9, 2016, and subsequently abandoned, which is a Continuation of U.S. patent application Ser. No. 14/209,889, filed on Mar. 13, 2014 and issued as U.S. Pat. No. 9,308,302, which claims the benefit of priority to U.S. Provisional Patent Application No. 61/798,590, filed on Mar. 15, 2013, all of which are hereby incorporated by reference herein.

BACKGROUND OF THE INVENTION

Field of the Invention

This application is directed to pumps for mechanical circulatory support of a heart. In particular, this application is directed to various implementations of a stator that can be used to enhance flow and/or performance of a catheter pump.

Description of the Related Art

Heart disease is a major health problem that has high mortality rate. Physicians increasingly use mechanical circulatory support systems for treating heart failure. The treatment of acute heart failure requires a device that can provide support to the patient quickly. Physicians desire treatment options that can be deployed quickly and minimally-invasively.

Intra-aortic balloon pumps (IABP) are currently the most common type of circulatory support devices for treating acute heart failure. IABPs are commonly used to treat heart failure, such as to stabilize a patient after cardiogenic shock, during treatment of acute myocardial infarction (MI) or decompensated heart failure, or to support a patient during high risk percutaneous coronary intervention (PCI). Circulatory support systems may be used alone or with pharmacological treatment.

In a conventional approach, an IABP is positioned in the aorta and actuated in a counterpulsation fashion to provide partial support to the circulatory system. More recently minimally-invasive rotary blood pump have been developed in an attempt to increase the level of potential support (i.e. higher flow). A rotary blood pump is typically inserted into the body and connected to the cardiovascular system, for example, to the left ventricle and the ascending aorta to assist the pumping function of the heart. Other known applications pumping venous blood from the right ventricle to the pulmonary artery for support of the right side of the heart. An aim of acute circulatory support devices is to reduce the load on the heart muscle for a period of time, to stabilize the patient prior to heart transplant or for continuing support.

There is a need for improved mechanical circulatory support devices for treating acute heart failure. Fixed cross-section ventricular assist devices designed to provide near full heart flow rate are either too large to be advanced percutaneously (e.g., through the femoral artery without a cutdown) or provide insufficient flow.

There is a need for a pump with improved performance and clinical outcomes. There is a need for a pump that can provide elevated flow rates with reduced risk of hemolysis and thrombosis. There is a need for a pump that can be inserted minimally-invasively and provide sufficient flow rates for various indications while reducing the risk of major adverse events. In one aspect, there is a need for a heart pump that can be placed minimally-invasively, for example, through a 15 FR or 12 FR incision. In one aspect, there is a need for a heart pump that can provide an average flow rate of 4 Lpm or more during operation, for example, at 62 mmHg of head pressure. While the flow rate of a rotary pump can be increased by rotating the impeller faster, higher rotational speeds are known to increase the risk of hemolysis, which can lead to adverse outcomes and in some cases death. Accordingly, in one aspect, there is a need for a pump that can provide sufficient flow at significantly reduced rotational speeds. These and other problems are overcome by the inventions described herein.

SUMMARY OF THE INVENTION

There is an urgent need for a pumping device that can be inserted percutaneously and also provide full cardiac rate flows of the left, right, or both the left and right sides of the heart when called for.

In one embodiment, a catheter pump assembly is provided that includes a proximal a distal portion, a catheter body, an impeller, and a flow modifying structure. The catheter body has a lumen that extends along a longitudinal axis between the proximal and distal portions. The impeller is disposed at the distal portion. The impeller includes a blade with a trailing edge. The flow modifying structure is disposed downstream of the impeller. The flow modifying structure has a plurality of blades having a leading edge substantially parallel to and in close proximity to the trailing edge of the blade of the impeller and an expanse extending downstream from the leading edge.

In some embodiments, the expanse has a first region with higher curvature and a second region with lower curvature. The first region is between the leading edge and the second region.

In some embodiments, the flow modifying structure is collapsible from a deployed configuration to a collapsed configuration.

In another embodiment, a catheter pump is provided that has an impeller and a stator. The impeller is disposed at a distal portion of the pump. The stator is disposed downstream of the impeller. The impeller is sized and shaped to be inserted into a vascular system of a patient through a percutaneous access site having a size less than about 21 FR. The catheter pump is configured to pump blood in the vascular system at physiological rates at speeds less than 25K RPM.

In another embodiment, a catheter pump assembly is provided that includes a proximal portion, a distal portion, a catheter body, and an impeller. The catheter body has a lumen that extends along a longitudinal axis between the proximal and distal portions. The impeller is disposed at the distal portion. The impeller includes a blade with a high angle to the longitudinal axis of the pump. The catheter pump assembly includes a flow modifying structure disposed downstream of the impeller. The flow modifying structure has a plurality of blades. The blades have a trailing edge that are inclined relative to a transverse plane intersecting the trailing edge. The flow modifying structure is collapsible from a deployed configuration to a collapsed configuration.

In some embodiment, the trailing edge of the impeller and the leading edge of the flow modifying structure are configured to minimize losses therebetween. For example, the gap between these structures can be maintained small to minimize turbulence at this boundary. Also, the angles of both structures to the longitudinal axis of the impeller and flow directing structure can be approximately the same, e.g., more than 60 degrees and in some cases approximately 90 degrees. The impeller includes a blade with a trailing edge at an angle of more than about 60 degrees to the longitudinal axis of the impeller.

In one embodiment, an impeller for a pump is disclosed. The impeller can comprise a hub having a proximal end portion and a distal end portion. A blade can be supported by the hub. The blade can have a fixed end coupled to the hub and a free end. Further, the impeller can have a stored configuration when the impeller is at rest, a deployed configuration when the impeller is at rest, and an operational configuration when the impeller rotates. The blade in the deployed and operational configurations can extend away from the hub. The blade in the stored configuration can be compressed against the hub. The blade can include a curved surface having a radius of curvature. The radius of curvature can be larger in the operational configuration than when the impeller is in the deployed configuration. The impeller can be used alone or in combination with a flow modifying device as discussed herein.

In another embodiment, a percutaneous heart pump is disclosed. The pump can comprise a catheter body and an impeller coupled to a distal end portion of the catheter body. The impeller can comprise a hub. A blade can be supported by the hub and can have a front end portion and a back end portion. The blade can include a ramped surface at the back end portion. A sheath can be disposed about the catheter body and can have a proximal end and a distal end. The distal end of the sheath can be configured to compress the blade from an expanded configuration to a stored configuration when the distal end of the sheath is urged against the ramped surface of the blade. In some variants, a flow modifying device is downstream of the impeller. In such variants, the ramped surface may be positioned on the flow modifying device or may be positioned on both the flow modifying device and the impeller.

In yet another embodiment, a method for storing an impeller is disclosed. The method can comprise urging a sheath against a ramped surface of a back end of a blade of an impeller. In some variants, a flow modifying structure is provided that may be distal or proximal of the impeller. If the flow modifying structure is proximal of the impeller, the method can comprise urging a sheath against a ramped surface of a back end of a blade of the flow modifying structure. The impeller can have one or more blades. Further, the impeller can have a stored configuration and a deployed configuration. Each blade in the stored configuration can be compressed against a hub of the impeller. Each blade in the deployed configuration can extend away from the hub. The method can further comprise collapsing the blade against the hub to urge the impeller into the stored configuration.

In another embodiment, a percutaneous heart pump system is disclosed. The system can comprise an impeller disposed at a distal portion of the system. The impeller can be sized and shaped to be inserted through a vascular system of a patient. The impeller can be configured to pump blood through at least a portion of the vascular system at a flow rate of at least about 3.5 liters per minute when the impeller is rotated at a speed less than about 21,000 revolutions per minute. In some cases, the percutaneous heart pump system can also have a flow modifying structure, e.g., a stator.

In another embodiment, a method of pumping blood through the vascular system of a patient is disclosed. The method can comprise inserting an impeller, with or without a flow modifying structure such as a stator, through a portion of the vascular system of the patient to a heart chamber. The method can further include rotating the impeller at a speed less than about 21,000 revolutions per minute to pump blood through at least a portion of the vascular system at a flow rate of at least about 3.5 liters per minute.

In yet another embodiment, an impeller configured for use in a catheter pump is provided. The impeller can comprise a hub having a distal portion, a proximal portion, and a diameter. The impeller can also include a blade having a fixed end at the hub and a free end. The blade can have a height defined by a maximum distance between the hub and the free end. A value relating to a ratio of the blade height to the hub diameter can be in a range of about 0.7 to about 1.45.

In another embodiment, a percutaneous heart pump system is provided. The system can comprise an impeller disposed at a distal portion of the system, the impeller sized and shaped to be inserted into a vascular system of a patient through a percutaneous access site having a size less than about 21 FR. The impeller can be configured to pump blood in the vascular system at a flow rate of at least about 3.5 liters per minute. In some variations, the heart pump system includes a flow modifying structure, such as a stator.

In another embodiment, a percutaneous heart pump system is disclosed. The system can include an impeller comprising one or more blades in a single row. The impeller can be disposed at a distal portion of the system. The impeller can be sized and shaped to be inserted through a vascular system of a patient. The impeller can be configured to pump blood through at least a portion of the vascular system at a flow rate of at least about 2.0 liters per minute when the impeller is rotated at a speed less than about 21,000 revolutions per minute. In some variations, the heart pump system includes a flow modifying structure, such as a stator.

BRIEF DESCRIPTION OF THE DRAWINGS

A more complete appreciation of the subject matter of this application and the various advantages thereof can be realized by reference to the following detailed description, in which reference is made to the accompanying drawings in which:

FIG. **1** illustrates one embodiment of a catheter pump configured for percutaneous application and operation;

FIG. **2** is a plan view of one embodiment of a catheter adapted to be used with the catheter pump of FIG. **1**;

FIGS. **3**A-**3**C illustrate the relative position of an impeller blade and an inner surface of an impeller housing in an undeflected configuration;

FIG. **4** shows the catheter assembly similar to that of FIG. **2** in position within the anatomy;

FIGS. **5**A-**5**F are three-dimensional (3D) perspective views of an impeller according to one embodiment;

FIG. **6** is a 3D perspective view of an impeller according to another embodiment;

FIG. **7** is a 3D perspective view of an impeller according to yet another embodiment;

FIG. **8** is a side view of an impeller according to another embodiment;

FIGS. **9A-9E** are side views of impellers according to various embodiments;

FIG. **10A** is a side view of an impeller according to yet another embodiment;

FIG. **10B** is a 3D perspective view of the impeller of FIG. **10A**;

FIG. **11** is a side view of an impeller according to another embodiment.

FIG. **12** is a schematic, side cross-sectional view of an impeller having a hub and one or more blades disposed within a housing.

FIG. **13** is a chart plotting flow rate versus motor speed for the impellers illustrated in FIGS. **10A-10B** and **9E**.

FIG. **14** is a chart plotting flow rate versus motor speed for the impeller of FIGS. **10A-10B** at a given pressure, as compared to various conventional microaxial, rotary pumps at the same or similar pressure.

FIG. **14A** is an H-Q curve relating to four catheter pumps.

FIG. **15** is a plan view of a distal portion of a catheter pump assembly.

FIG. **16** is perspective view of a stator assembly.

FIG. **17** is a first side view of a stator assembly.

FIG. **18** is a second side view of a stator assembly.

FIG. **19** is an end view of a stator assembly.

More detailed descriptions of various embodiments of components for heart pumps useful to treat patients experiencing cardiac stress, including acute heart failure, are set forth below.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT

This application is directed to apparatuses for inducing motion of a fluid relative to the apparatus. In particular, the disclosed embodiments generally relate to various configurations for an impeller disposed at a distal portion of a percutaneous catheter pump. For example, FIGS. **1-4** show aspects of an exemplary catheter pump **10** that can provide high performance flow rates. The exemplary pump **10** includes a motor driven by a controller **22**. The controller **22** directs the operation of the motor **14** and an infusion system **26** that supplies a flow of infusate in the pump **10**. A catheter system **80** that can be coupled with the motor **14** houses an impeller within a distal portion thereof. In various embodiments, the impeller is rotated remotely by the motor **14** when the pump **10** is operating. For example, the motor **14** can be disposed outside the patient. In some embodiments, the motor **14** is separate from the controller **22**, e.g., to be placed closer to the patient. In other embodiments, the motor **14** is part of the controller **22**. In still other embodiments, the motor is miniaturized to be insertable into the patient. Such embodiments allow the drive shaft to be much shorter, e.g., shorter than the distance from the aortic valve to the aortic arch (about 5 cm or less). Some examples of miniaturized motors catheter pumps and related components and methods are discussed in U.S. Pat. Nos. 5,964,694; 6,007,478; 6,178,922; and 6,176,848, all of which are hereby incorporated by reference herein in their entirety for all purposes.

FIG. **4** illustrates one use of the exemplary catheter pump **10**. A distal portion of the pump **10**, which can include an impeller assembly **92**, is placed in the left ventricle (LV) of the heart to pump blood from the LV into the aorta. The pump **10** can be used in this way to treat patients with a wide range of conditions, including cardiogenic shock, myocardial infarction, and other cardiac conditions, and also to support a patient during a procedure such as percutaneous coronary intervention. One convenient manner of placement of the distal portion of the pump **10** in the heart is by percutaneous access and delivery using the Seldinger technique or other methods familiar to cardiologists. These approaches enable the pump **10** to be used in emergency medicine, a catheter lab and in other non-surgical settings. Modifications can also enable the pump **10** to support the right side of the heart. Example modifications that could be used for right side support include providing delivery features and/or shaping a distal portion that is to be placed through at least one heart valve from the venous side, such as is discussed in U.S. Pat. Nos. 6,544,216; 7,070,555; and U.S. 2012-0203056A1, all of which are hereby incorporated by reference herein in their entirety for all purposes.

FIG. **2** shows features that facilitate small blood vessel percutaneous delivery and high performance, including up to and in some cases exceeding normal cardiac output in all phases of the cardiac cycle. In particular, the catheter system **80** includes a catheter body **84** and a sheath assembly **88**. The impeller assembly **92** is coupled with the distal end of the catheter body **84**. The exemplary impeller assembly **92** is expandable and collapsible. In the collapsed state, the distal end of the catheter system **80** can be advanced to the heart, for example, through an artery. In the expanded state, the impeller assembly **92** is able to pump blood at high flow rates. FIGS. **2-4** illustrate the expanded state. The collapsed state can be provided by advancing a distal end **94** of an elongate body **96** distally over the impeller assembly **92** to cause the impeller assembly **92** to collapse. This provides an outer profile throughout the catheter assembly **80** that is of small diameter, for example, to a catheter size of about 12.5 FR in various arrangements. Although various expandable impellers are disclosed herein (e.g., impellers having a stored configuration and a deployed configuration), it should be appreciated that the principles described below may also be applicable to impellers that may not be expandable or collapsible. For example, the impeller parameters described herein may also be applicable to fixed diameter impellers in some arrangements.

In some embodiments, the impeller assembly **92** includes a self-expanding material that facilitates expansion. The catheter body **84** on the other hand preferably is a polymeric body that has high flexibility. When the impeller assembly **92** is collapsed, as discussed above, high forces are applied to the impeller assembly **92**. These forces are concentrated at a connection zone, where the impeller assembly **92** and the catheter body **84** are coupled together. These high forces, if not carefully managed can result in damage to the catheter assembly **80** and in some cases render the impeller within the impeller assembly **92** inoperable. Robust mechanical interface, are provided to assure high performance.

The mechanical components rotatably supporting the impeller within the impeller assembly **92** permit high rotational speeds while controlling heat and particle generation that can come with high speeds. The infusion system **26** delivers a cooling and lubricating solution to the distal portion of the catheter system **80** for these purposes. However, the space for delivery of this fluid is extremely limited. Some of the space is also used for return of the infusate. Providing secure connection and reliable routing of infusate into and out of the catheter assembly **80** is critical and challenging in view of the small profile of the catheter body **84**.

When activated, the pump **10** can effectively increase the flow of blood out of the heart and through the patient's vascular system. In various embodiments disclosed herein, the pump **10** can be configured to produce a maximum flow rate (e.g. low mm Hg) of greater than 4 Lpm, greater than

4.5 Lpm, greater than 5 Lpm, greater than 5.5 Lpm, greater than 6 Lpm, greater than 6.5 Lpm, greater than 7 Lpm, greater than 7.5 Lpm, greater than 8 Lpm, greater than 9 Lpm, or greater than 10 Lpm. In various embodiments, the pump can be configured to produce an average flow rate at about 62 mmHg during operation of greater than 2 Lpm, greater than 2.5 Lpm, greater than 3 Lpm, greater than 3.5 Lpm, greater than 4 Lpm, greater than 4.5 Lpm, greater than 5 Lpm, greater than 5.5 Lpm, or greater than 6 Lpm. In various embodiments, the pump can be configured to produce an average flow rate of at least about 4.25 Lpm at 62 mmHg. In various embodiments, the pump can be configured to produce an average flow rate of at least about 4 Lpm at 62 mmHg. In various embodiments, the pump can be configured to produce an average flow rate of at least about 4.5 Lpm at 62 mmHg. Flow modifying structures, such as fins or blades, which can be implemented in a stator, can be provided higher peak flow rate output by the pump **10** as discussed below.

Various aspects of the pump and associated components are similar to those disclosed in U.S. Pat. Nos. 7,393,181, 8,376,707, 7,841,976, 7,022,100, and 7,998,054 and U.S. Pub. Nos. 2011/0004046, 2012/0178986, 2012/0172655, 2012/0178985, and 2012/0004495, the entire contents of which are incorporated herein for all purposes by reference. In addition, this application incorporates by reference in its entirety and for all purposes the subject matter disclosed in each of the following concurrently filed applications: application Ser. No. 13/802,556, which corresponds to attorney docket no. THOR.072A, entitled "DISTAL BEARING SUPPORT," filed on Mar. 13, 2013; application Ser. No. 61/780,656, which corresponds to attorney docket no. THOR.084PR2, entitled "FLUID HANDLING SYSTEM," filed on Mar. 13, 2013; application Ser. No. 13/801,833, which corresponds to attorney docket no. THOR.089A, entitled "SHEATH SYSTEM FOR CATHETER PUMP," filed on Mar. 13, 2013; application Ser. No. 13/801,528, which corresponds to attorney docket no. THOR.092A, entitled "CATHETER PUMP," filed on Mar. 13, 2013; and application Ser. No. 13/802,468, which corresponds to attorney docket no. THOR.093A, entitled "MOTOR ASSEMBLY FOR CATHETER PUMP," filed on Mar. 13, 2013.

Blade & Impeller Configurations

With reference to FIGS. **3**A-**3**C, an operative device of the pump can include an impeller **300** having one or more blades **303**. The one or more blades **303** can extend from an impeller hub **301**. It can be desirable to increase the flow rate of the heart pump while ensuring that the impeller **300** can be effectively deployed within a subject. For example, an impeller can include one or more blades **303** that are configured to be inserted into a subject in a stored, or compressed, configuration. When the impeller **300** is positioned in the desired location, e.g., a chamber of a subject's heart as shown in FIG. **4**, the blade(s) **303** of the impeller **300** can self-expand into a deployed or expanded configuration, in which the blade(s) **303** extends radially from a hub **301**.

As shown in FIGS. **3**A-**3**B, the impeller **300** can be positioned within a cannula or housing **202**. A free end of the blades **303** can be separated from the wall W of the housing **202** by a tip gap G. The housing **202** can also have a stored, or compressed configuration, and a deployed or expanded configuration. The housing **202** and impeller **300** may deploy from the stored configurations from within a sheath or sleeve (not shown) into the expanded configuration. In such implementations, the sheath or sleeve can keep the blade(s) **303** and the housing **202** compressed until the blade(s) **303** and housing **202** are urged from within a storage cavity of the sheath or sleeve. Once the blade(s) **303** are released from the storage cavity of the sheath, the blade(s) **303** can self-expand to a deployed configuration using strain energy stored in the blades **303** due to deformation of the blade(s) **303** within the sheath or sleeve. The expandable housing **202** may also self-deploy using stored strain energy after being urged from the sheath.

In the stored configuration, the impeller **300** and housing **202** have a diameter that is preferably small enough to be inserted percutaneously into a patient's vascular system. Thus, it can be advantageous to fold the impeller **300** and housing **202** into a small enough stored configuration such that the housing **202** and impeller **300** can fit within the patient's veins or arteries. In some embodiments, therefore, the impeller **300** can have a diameter in the stored configuration corresponding to a catheter size between about 8 FR and about 21 FR. In one implementation, the impeller **300** can have a diameter in the stored state corresponding to a catheter size of about 9 FR. In other embodiments, the impeller **300** can have a diameter in the stored configuration between about 12 FR and about 21 FR. For example, in one embodiment, the impeller **300** can have a diameter in the stored configuration corresponding to a catheter size of about 12 FR or about 12.5 FR.

When the impeller **300** is positioned within a chamber of the heart, however, it can be advantageous to expand the impeller **300** to have a diameter as large as possible in the expanded or deployed configuration. In general, increased diameter of the impeller **300** can advantageously increase flow rate through the pump. In some implementations, the impeller **300** can have a diameter corresponding to a catheter size greater than about 12 FR in the deployed configuration. In other embodiments, the impeller **300** can have a diameter corresponding to a catheter size greater than about 21 FR in the deployed or expanded configuration.

In various embodiments, it can be important to increase the flow rate of the heart pump while ensuring that the operation of the pump does not harm the subject. For example, increased flow rate of the heart pump can advantageously yield better outcomes for a patient by improving the circulation of blood within the patient. Furthermore, the pump should avoid damaging the subject. For example, if the pump induces excessive shear stresses on the blood and fluid flowing through the pump (e.g., flowing through the cannula), then the impeller can cause damage to blood cells, e.g., hemolysis. If the impeller damages a large number of blood cells, then hemolysis can lead to negative outcomes for the subject, or even death. As will be explained below, various blade parameters can affect the pump's flow rate as well as conditions within the subject's body. Also, flow modifying structures such as stationary fins or blades, e.g., as part of a stator, can enhance the performance and/or efficiency of the pump **10**. In some arrangements, a stator may change the direction of flow, e.g., from a substantial portion circumferential to primarily axial direction. In some arrangements, the stator may modify the flow, e.g., to realign a complex flow field into a more uniform, laminar flow. This is sometimes referred to as smoothing out the flow or reducing turbulence. In this case, the stator may also serve to convert the kinetic energy of the complex flow field in the region of the trailing edges of the impeller into pressure before it is directed back into the circulatory system. This has been found to improve hydraulic efficiency because the complex, rotational flow field energy would normally be dissipated in the pump. In some arrangements, the stator may realign and redirect the flow. These embodiments enable the pump **10** to create a greater pressure head (i.e. pressure differential) at the same rotational speed and back-pressure. In turn, the clinician can advantageously adjust the pump to improve patient outcomes. The clinician can obtain a higher pressure head (H) at the same flow rate. Alternatively, the clinician may be able to obtain a higher flow rate (Q) with the same head pressure. The clinician may also be able to achieve improves to both H and Q. The pump may also be maintained the same head pressure and flow rate at a lower rotational speed. Lowering the rotational speed can reduce hemolysis risk. Thus, pump **10** demonstrates significant performance improvements compared to a pump without these structures. These improvements to performance translate into improvements in clinical outcomes and expand the range of clinical applications of the pump.

Overview of Various Embodiments

Various embodiments of an impeller for use in a heart pump are disclosed herein and the various impellers can be combined with a stator for enhanced performance as described further herein. Before discussing the combination of impellers and stators, various aspects of impeller embodiments will be discussed. In particular, FIGS. **5A-11** illustrate different configurations for an impeller **300-300J**. Each of the disclosed impellers **300-300J** can be defined by several different characteristics or parameters that can advantageously improve flow rate while achieving healthy outcomes in a patient. Further, various properties or characteristics of the disclosed impellers may assist in storing and/or deploying the impeller into and/or out from an outer sleeve. Each figure may only illustrate a few of the characteristics of the impeller for ease of illustration. However, it should be appreciated that each illustrated impeller may be associated with all of the characteristics or properties disclosed herein. For example, some figures may illustrate only a few angles or other geometric or structural properties of the impeller, but it should be appreciated that all the impellers disclosed herein may be associated with the disclosed characteristics or properties (see, e.g., the example values given in Tables 1 and 2).

In order to improve patient outcomes, it can be advantageous to provide a heart pump capable of pumping blood at high flow rates while minimizing damage to the blood or the patient's anatomy. For example, it can be desirable to increase flow rate while reducing the motor speed, as higher motor speeds are known to increase the hemolysis risk. Furthermore, for percutaneous insertion heart pump systems, it can be advantageous to make the diameter of the impeller and the cannula as small as possible for insertion into the patient's vasculature. Accordingly, the various impeller embodiments disclosed herein can provide high flow rate while maintaining a diameter small enough for insertion into the patient's vasculature and while reducing the risk that the patient's anatomy and blood are damaged during operation of the pump.

For the impellers **300-300J** illustrated in FIGS. **5A-11**, for example, the blades **303** may be formed to have a curved profile with a radius of curvature, R. The radius of curvature R may be sized such that, when the impeller is in the stored or compressed configuration, the blades **303** conform closely to the hub **301**. Indeed, in various arrangements, the blades **303** in the stored configuration can have a radius R_S sized such that the blades **303** lie against the hub **301** in a low profile so that the insertion diameter of the catheter pump is small enough to be safely inserted through the patient's vasculature. In some embodiments, the radius of curvature R and/or the height h of the blade **303** are selected such that neighboring blades in a particular blade row do not overlap when the impeller is in the stored configuration. By reducing or eliminating blade overlap in the stored configuration, the insertion diameter of the catheter pump can be reduced. In other arrangements, however, neighboring blades may overlap in the stored configuration.

Furthermore, when the impeller is urged out of an external sleeve, the impeller can self-expand into a deployed configuration, in which the impeller is deployed from the sleeve and expanded into a deployed diameter larger than a stored diameter. In various embodiments, the self-expansion of the impeller can be induced by strain energy stored in the blades **303**, such as strain or potential energy stored near the root of the blades **303**. When the sleeve is urged away from the impeller, the blades **303** can be free to expand into the deployed configuration. It should be appreciated that when the blades **303** are in the deployed configuration, the blade(s) **303** can be in a relaxed state, such that there are no or minimal external forces (such as torque- or flow-induced loads) and internal forces (such as strain energy stored in the blades) applied to the impeller or blades. A radius of curvature R_D of the blades **303** in the deployed configuration may be selected to improve flow characteristics of the pump while reducing the risk of hemolysis or other damage to the patient. For example, in some embodiments, the impeller can be molded to form blades **303** having the desired deployed radius of curvature R_D, such that in a relaxed (e.g., deployed) state, the blades **303** have a radius of curvature R_D that may be selected during manufacturing (e.g., molding). In some arrangements, the radius of curvature R_D of the blades in the deployed configuration may be about the same as the radius of curvature R_S of the blades in the stored configuration. In other arrangements, however, the radius of curvature of the blades **303** in the stored and deployed configurations may be different.

When the heart pump is activated to rotate the impeller, the impeller and blades **303** may be in an operational configuration. In the operational configuration, the impeller may rotate to drive blood through the housing **202**. The rotation of the impeller and/or the flow of blood past the impeller can cause the blades **303** to deform such that an operational radius of curvature R_o may be induced when the impeller is in the operational configuration. For example, when the impeller rotates, the blades **303** may slightly elongate such that the free ends of the blades **303** extend further radially from the hub **301** relative to when the blades **303** are in the deployed configuration. As the blades **303** deform radially outward in the operational configuration, the operational radius of curvature R_o may therefore be larger than the deployed radius of curvature R_D. For example, in some embodiments, in the operational configuration, the blades **303** may substantially flatten such that there is little curvature of the blades during operation of the pump. Indeed, in the operational configuration, the blades **303** may extend to an operational height h_o that is larger than the height h of the blades **303** when in the deployed configuration (see h as illustrated in the impellers **300-300J** of FIG. **5A-11**, which are in a deployed or relaxed configuration). In some embodiments, because the blades **303** may be manufactured to be relaxed when in the deployed configuration, the radius of curvature R_D and the height h of the blades **303** in the deployed configuration can be selected such that, in the operational configuration, the blades **303** extend radially outward from the hub **301** as far as possible without risking an overly small tip gap G (see FIG. **3**C). Flow rate can be improved by enabling the blades **303** to extend radially outward to a greater extent in the operational configuration than in the deployed configuration.

It should be appreciated that the various parameters described herein may be selected to increase flow rate, even while reducing the rotational speed of the impeller. For example, even at relatively low impeller rotational rates of 21,000 revolutions per minute (RPM) or less (e.g., rates in a range of about 18,000 RPM to about 20,000 RPM, or more particularly, in a range of about 18,500 RPM to about 19,500 RPM in some arrangements), the blades **303** can be designed to yield relatively high flow rates in a range of about 4 liters/minute (LPM) to about 5 liters/minute. Conventional percutaneous rotary blood pumps have been found to deliver less than ideal flow rates even at rotational speeds in excess of 40,000 RPM. It should be appreciated that higher impeller rotational rates may be undesirable in some aspects, because the high rate of rotation, e.g., higher RPMs, lead to higher shear rates that generally increase hemolysis and lead to undesirable patient outcomes. By reducing the impeller rotational rate while maintaining or increasing flow rate, the pump in accordance with aspects of the invention can reduce the risk of hemolysis while significantly improving patient outcomes over conventional designs.

Furthermore, to enable percutaneous insertion of the operative device of the pump into the patient's vascular system, the impellers **300**-**300**J disclosed herein in FIGS. **5**A-**11** may also include a ramped surface at a rearward or proximal end of the blade. As explained herein (see, e.g., FIG. **12**), when the external sleeve is urged against the housing **202** (e.g., cannula), the external sleeve can press against the housing **202** and the ramped surface of the impeller to collapse the impeller and blades into the stored configuration. For example, the ramped surface can be used to store the blades and impeller after assembly of the pump for packaging purposes and/or after performing a heart pumping procedure for withdrawal of the pump from the anatomy.

The impellers disclosed herein may be formed of any suitable material and by any suitable process. For example, in preferred embodiments, the impeller is formed from a flexible material, e.g., an elastic material such as a polymer. Any suitable polymer can be used. In some embodiments, for example, Hapflex™ 598, Hapflex™ 798, or Steralloy™ or Thoralon™ may be used in various portions of the impeller body. In some arrangements, the impeller body can be molded to form a unitary body.

Various Impeller Designs

Turning to FIGS. **5**A-**5**F, one embodiment of the impeller **300** is presented. It should be appreciated that FIGS. **5**A-**5**F illustrate the same impeller **300**, only showing different views and impeller parameters for ease of illustration. One or more blades **303** can extend from the hub **301**, such that a fixed end of the blades **303** is integrally formed with or coupled to the hub **301**. The blades **303** can also have a free end located at the tip of the blades **303**. As used herein, therefore, it should be appreciated that the blades **303** can have a fixed end coupled to the hub **301** (e.g., at a blade root) and a free end at a tip of the blade **303**. In the illustrated embodiments, the hub **301** and blades **303** form a single unitary, or monolithic, body. However, it should be appreciated that in other embodiments, the hub **301** and blades **303** may be formed from separate components or materials. In various implementations, the impeller **300** can include one or more blade rows extending along the hub **301**.

FIGS. **5**A-**5**F illustrate the impeller **300** having one blade row and two blades **303**. The hub **301** can have a first diameter D_1 at a distal end portion of the impeller **300** (e.g., near a leading edge of the blade(s) **303**) and a second diameter D_2 at a proximal end portion of the impeller **300** (e.g., near a trailing edge of the blade(s) **303**). As used herein and as shown in FIG. **5**A, for example, a distal end portion of the impeller **300** may be disposed nearer the distal end of the catheter pump, while a proximal end portion of the impeller **300** may be disposed nearer the motor and the insertion site. As explained below, in some implementations, D_1 can be less than D_2. The hub **301** can also have a length L, and the blades **303** can have a height h, which can be the distance between the hub and the free end of the blades. Further, each blade **303** can have a blade length L_b, which may or may not be the same as the hub length L. As shown in FIG. **5**A, the height h may be measured from the hub **301** to the free end of a middle portion of the blades **303** when the impeller is in a deployed or relaxed configuration. The height h may vary along the length of the blades **303**, e.g., increasing proximally from a forward or distal end of the blades **303** to a maximum in a middle portion of the blades and decreasing from the middle portion to a rearward or proximal portion of the blades. Furthermore, as explained above, when the impeller **300** rotates and is in an operational configuration, the operational height h_o may be larger than the blade height h in the deployed or relaxed configuration, which is illustrated in FIGS. **5**A-**5**F.

Furthermore, each blade **303** can include a suction side **305** and a pressure side **307**. In general, fluid can flow from the suction side **305** of the blade **303** toward the pressure side **307** of the blade **303**, e.g., from the distal end portion of the impeller **300** to the proximal end portion of the impeller **300**. The pressure side **307** can be include a curved, concave surface having a predetermined radius of curvature R, as best seen in FIG. **5**C, and as explained above. For example, in FIGS. **5**A-**5**F, the illustrated radius of curvature R corresponds to a relaxed or deployed radius of curvature R_D. As explained above, when the impeller **300** rotates, the impeller may be in an operational configuration having an operational radius of curvature R_o that may be larger than the deployed radius of curvature R_D. Indeed, in some embodiments, the blades **303** may substantially flatten and elongate radially such that there is little curvature. The elongated blades **303** in the operational configuration may enable for increased flow rate through the pump.

Moreover, each blade **303** can have a thickness designed to improve impeller performance. As shown in FIG. **5**B, the leading edge or distal end portion of the blade **303** can have a first thickness t_{1a} at the fixed end of the blade **303**, where the blade **303** joins the hub **301**, and a second thickness t_{1b} at the free end of the blade **303**. Similarly, in FIG. **5**C, the trailing edge of the blade **303** can also have a first thickness t_{2a} at the fixed end of the blade **303** and a second thickness t_{2b} at the free end of the blade **303**. Example parameters for various blades in FIGS. **5**A-**11** will be disclosed in the description below and in Tables 1 and 2.

Each blade **303** can wrap around the hub **301** by a desired wrapping angle. The wrapping angle can be measured along the circumference of the hub **301**. As shown in the illustrated embodiments, each blade **303** can separately track a helical pattern along the surface of the hub **301** as the blade **303** wraps around the hub **301** along the length L of the hub. Table 2 and the disclosure below illustrate example wrapping angles for blades **303** in various embodiments. The blades can wrap around the hub any suitable number of turns or fractions thereof. Further, a first fillet **311** can be formed at the fixed end of each blade on the suction side **305**, and a second fillet **313** can be formed at the fixed end of each blade **303** on the pressure side **307**. As shown each fillet **311**, **313** can follow the fixed end of each blade **303** as it wraps around the hub **301**. As explained below, the first fillet **311** can be sized and shaped to provide support to the blade **303** as the impeller **300** rotates. The second fillet **313** can be sized and shaped to assist in folding or compressing the blade **303** into the stored configuration.

In addition, each blade **303** can form various blade angles α, β, and γ. As shown in FIGS. **5**D-F, the blade angles α (referred to herein as an "attack angle α" or a "distal blade angle α"), β (referred to herein as a "middle blade angle β"), and γ (referred to herein as a "proximal blade angle γ") measure the angles between a blade centerline at various portions of the blade and a plane that is perpendicular to the hub **301**. For example, the attack angle α can measure the angle between a plane formed perpendicular to the blade near the distal portion of the blade (e.g., distally along the impeller hub in FIG. **5**D) and a plane formed perpendicular to the hub **301**. The attack angle α can range between about 30 degrees and about 60 degrees. In some implementations, α can range between about 40 degrees and about 55 degrees. In the implementation of FIG. **5**D, for example, α can be in a range of about 48 degrees and about 52 degrees, e.g., about 50 degrees. The middle blade angle β can measure the angle between a plane perpendicular to the blade in a middle portion of the blade and a plane perpendicular to the hub **301**. In some implementations, β can range from about 30 degrees to about 45 degrees. In the implementations of FIGS. **5**A-**5**F and **6**, for example, β can be in a range of about 35 degrees and about 42 degrees, e.g., about 40 degrees. The proximal blade angle γ can correspond to the angle between a plane perpendicular to the blade in a proximal portion of the blade (e.g., proximal with respect to the hub **301**) and a plane perpendicular to the hub **301**. In some embodiments, γ can range between about 25 degrees and about 55 degrees. In the illustrated embodiment of FIG. **5**F, γ can be in a range of about 30 degrees and about 40 degrees, or about 35 degrees, for example. In some embodiments, the attack angle α can be larger than the middle blade angle β. Further, in some embodiments, the middle blade angle can be larger than the proximal blade angle γ. In some embodiments, the attack angle α can be larger than both the middle blade angle β and the proximal blade angle γ. The blade angles α, β, and γ can be further designed using computational techniques to maintain desired flow characteristics, such as flow rate, pressure head, and rotational speed. For example, the disclosed blade angles can, in various impellers disclosed herein, enable flow rates in a range of about 4 liters/minute to about 5.5 liters/minute, when the impeller rotates at a speed below about 20,000 RPMs (e.g., in a range of about 19,000 RPMs to about 21,000 RPMs in some arrangements). By maintaining a high flow rate at relatively low rotational speeds, the disclosed impellers can achieve desirable patient outcomes while reducing the risk of hemolysis and increasing pump reliability.

Further, the trailing edge of each blade **303** can include a ramp **315** forming a ramp angle θ with the plane perpendicular to the hub **301**, as best illustrated in FIG. **5**C. The ramp **315** can be shaped such that when the sheath and housing **202** are urged against the ramp **315**, or when the blades **303** and housing **202** are pulled proximally relative to and into the sheath, the axial force applied by the sheath can be transferred downward by the ramp **315** to assist in folding the blade **303** against the hub **301**. The ramp angle θ can be configured to assist in folding the blade **303** against the hub **301**. Further, the cross-sectional curvature and/or axial form of the blades can also be configured to reduce the force needed to collapse the impeller when used in conjunction with the ramp angle θ. For example, the angle that the blades twist around the hub may be configured to direct axial forces applied by the sheath to fold the blades against the hub **301**. The radius of curvature R of the blades **303** can also be selected to enable the blades **303** to conform closely to the hub **301**, as explained above.

Turning to FIGS. **6**-**11**, other embodiments of the impeller **300** are illustrated. Reference numerals in FIGS. **6**-**11** generally represent components similar to those of FIGS. **5**A-**5**F. In addition, it should be appreciated that the parameters and angles described above with reference to FIGS. **5**A-**5**F are also present in the impellers disclosed in FIGS. **6**-**11**, even where such parameters or angles are not specifically referenced for ease of illustration. For example, FIG. **6** illustrates an impeller **300**A having two blades **303** in one blade row. On the other hand, FIG. **7** illustrates an impeller **300**B having three blades **303** in a single blade row. FIG. **8** illustrates another example of an impeller **300**C having two blades **303** in one blade row. FIGS. **9**A-**9**C illustrate three impellers **300**F-**300**H, respectively, each having two blades in one row. FIG. **9**D illustrates an impeller **3001** having three blades in one row. By contrast, FIG. **9**E shows an impeller **300**J having four blades total, with two blade rows, each blade row having two blades. FIGS. **10**A-**10**B illustrate yet another impeller **300**D having three blades **303** in a single row, while FIG. **11** shows an impeller **300**E having two blades **303** in a single row. Tables 1 and 2 include various properties for the impellers **300** shown in the embodiments of FIGS. **5**A-**5**C and **6**-**11**. The impellers **300**-**300**J disclosed herein may have different values for the various parameters and characteristics disclosed herein, and some of the impellers may have improved performance relative to other of the disclosed impellers.

The impellers **300** illustrated in the disclosed embodiments may have other features. For example, for impellers with multiple blade rows, the blade(s) in one row may be angularly clocked relative to the blade(s) in another row. It should be appreciated that the blades may be configured in any suitable shape or may be wrapped around the impeller hub in any manner suitable for operation in a catheter pump system.

Impeller Parameters

As explained above, various impeller parameters can be important in increasing flow rate while ensuring that the pump operates safely within the subject. Further, various properties and parameters of the disclosed impellers **300**-**300**J of FIGS. **5**A-**11** may enable the impellers to more easily collapse into the stored configuration. Similarly, with regard to FIGS. **15**-**19**, features of stators enhancing these and other aspects are discussed below.

Hub Diameter and Length

One impeller parameter is the size of the hub, e.g., the diameter and/or the length of the hub. As illustrated in FIGS. **5**A-**11**, the hub can be tapered in various embodiments, such that the distal end portion of the hub has a first diameter, D_1, and the proximal end portion of the hub has a second diameter, D_2. The first and second diameters, D_1 and D_2 can determine the spacing between the wall W of the housing

202 and the hub 301. Since the housing 202 effectively bounds the area through which blood can flow, the spacing between the hub 301 and the housing wall W may determine the maximum flow rate through the pump. For example, if the hub 301 has a relatively small diameter, then the flow area between the inner wall W of the housing 202 and the hub 301 may be larger than in embodiments with a larger hub diameter. Because the flow area is larger, depending on other impeller parameters, the flow rate through the pump may advantageously be increased.

One of skill in the art will appreciate from the disclosure herein that the impeller parameters may be varied in accordance with the invention. For a known pressure, blade height, h, and impeller angular velocity, ratios of D_1 to D_2 can be determined to provide the desired flow rate, Q. The hub diameter can vary. In some embodiments, D_1 can range between about 0.06 inches and about 0.11 inches. D_2 can range between about 0.1 inches and about 0.15 inches. For example, in the impeller shown in FIGS. **5A-5F**, D_1 can be about 0.081 inches, and D_2 can be about 0.125 inches. In the implementation of FIGS. **10A** and **10B**, D_1 can be in a range of about 0.08 inches and about 0.09 inches (e.g., about 0.0836 inches in some arrangements), and D_2 can be in a range of about 0.12 inches and about 0.13 inches (e.g., about 0.125 inches in some arrangements).

Moreover, the length, L_b, of each blade can be designed in various embodiments to achieve a desired flow rate and pressure head. In general, longer blades can have higher flow rates and pressure heads. Without being limited by theory, it is believed that longer blades can support more blade material and surface area to propel the blood through the cannula. Thus, both the length of the blades and the first and second diameters D_1 and D_2 can be varied to achieve optimal flow rates. For example, D_1 can be made relatively small while L_b can be made relatively long to increase flow rate.

Blade Height

Another impeller parameter is the height h of the blades of the impeller in the deployed, or relaxed, configuration. The height h of the blades can be varied to achieve a stable flow field and to reduce turbulence, while ensuring adequate flow rate. For example, in some embodiments, the blade can be formed to have a height h large enough to induce adequate flow through the cannula. However, because the blades are preferably flexible so that they can fold against the hub in the stored configuration, rotation of the impeller may also cause the blades to flex radially outward due to centrifugal forces. As explained above with respect to FIGS. **3A-3C**, the tip gap G between the wall W of the housing **202** and the free ends of the blades can be quite small. If the blades **303** flex outwardly by a substantial amount when the impeller **300** rotates, then the distal ends of the blades **303** may impact the housing wall W, which can damage blood cells passing by. Thus, the height h may also be formed to be sufficiently small such that, upon rotation of the impeller **300**, deformation of the blades **300** still maintains adequate tip gap G.

On the other hand, as explained above, the height h of the blades **303** in the deployed configuration can be selected such that when the impeller rotates, the tip or free end of the blades **303** can extend or elongate to an operational height h_o, which extends further radially than when in the deployed configuration, in order to increase flow rate. Thus, as explained herein, the height h and the radius of curvature R_D of the blades **303** in the deployed configuration can be selected to both increase flow rate while reducing the risk of hemolysis caused by inadequate tip gap G.

In various implementations, the height of the blades near the middle of the impeller hub can range between about 0.06 inches and about 0.15 inches, for example, in a range of about 0.09 inches to about 0.11 inches. Of course, the height of the blades can be designed in conjunction with the design of the hub diameters and length, and with the radius of curvature R. As an example, for the impeller in FIGS. **5A-5C**, the height h of the blade near the middle of the impeller hub can be in a range of about 0.09 inches and about 0.1 inches (e.g., about 0.0995 inches in some arrangements). In the impeller of FIGS. **10A-10B**, the height h of the blade can be in a range of about 0.1 inches and about 0.11 inches (e.g., about 0.107 inches in some arrangements). Other example blade heights may be seen in Table 1.

Number of Blades

As mentioned above, impellers **300** can have any suitable number of blades **303**. In general, in impellers with more blades **303**, the flow rate of blood flowing through the cannula or housing **202** can be advantageously increased while reducing the required angular velocity of the drive shaft. Thus, absent other constraints, it can be advantageous to use as many blades as possible to maximize flow rate. However, because the impellers disclosed herein can be configured to fold against the hub **301** in the stored configuration for insertion into a patient's vasculature, using too many blades **303** can increase the overall volume of the impeller in the stored configuration. If the thickness of the impeller **300** in the stored configuration exceeds the diameter of the sheath or sleeve (or the diameter of the patient's artery or vein), then the impeller **300** may not collapse into the sheath for storing.

Moreover, increasing the number of blades **303** accordingly increases the number of shear regions at the free end of the blades **303**. As the impeller **300** rotates, the free ends of the blades **303** induce shear stresses on the blood passing by the blades **303**. In particular, the tip or free edge of the blades **303** can induce significant shear stresses. By increasing the overall number of blades **303**, the number of regions with high shear stresses are accordingly increased, which can disadvantageously cause an increased risk of hemolysis in some situations. Thus, the number of blades can be selected such that there is adequate flow through the pump, while ensuring that the impeller **300** can still be stored within the sheath and that the blades **303** do not induce excessive shear stresses. In various arrangements, for example, an impeller having three blades (such as the impellers shown in FIGS. **7**, **9D**, and **10A-10B**) can achieve an appropriate balance between increased flow rate and reduced risk of hemolysis.

Radius of Curvature

Yet another design parameter for the impeller is the radius of curvature, R, of the blades **303** on the pressure side **307** of the blades, as explained in detail above. As shown in FIGS. **5A-11**, the illustrated impellers **300-300J** are in the deployed configuration, such that the illustrated R corresponds to the deployed radius of curvature R_D. The radius of curvature R can be designed to minimize turbulence, while increasing flow rate. Turbulence can disadvantageously dissipate energy as the impeller rotates, which can reduce the flow rate. In general, higher curvature on the pressure side **307** of the blades **303** can increase turbulence. Moreover, the radius of curvature R can be designed to conform to the hub **301** such that, when the impeller is compressed by the sheath or sleeve, the curved pressure side **307** of the blade **303** conforms to the curvature of the hub **301** when the blades **303** are folded against the hub. Thus, the radius of curvature R of the blades can be designed to both reduce turbulent flow and to assist in folding the blades against the hub to ensure that the impeller **300** fits within the sheath in the stored configuration.

In addition, as explained above, when the impeller rotates and is in the operational configuration, the free end of the blades **303** may extend radially outward such that the radius of curvature in the operational configuration, R_o, may be higher than the radius of curvature in the operational configuration, R_D, which is illustrated as R in FIGS. **5**A-**11**. Indeed, the straightening and elongation of the blades **303** in the operational configuration may advantageously increase flow rate through the pump system.

The radius of curvature can range between about 0.06 inches and about 0.155 inches in various embodiments. In some embodiments, the radius of curvature can range between about 0.09 inches and about 0.14 inches. For example, in the implementation of FIGS. **5**A-**5**C, the cross-sectional radius of curvature R at the leading edge of the blades can be in a range of about 0.11 inches and about 0.13 inches (e.g., about 0.12 inches in some arrangements). By comparison, the radius of curvature R of the leading edge of the blades in the impeller **300** shown in FIGS. **10**A-**10**B (in the deployed configuration) can be in a range of about 0.13 inches to about 0.14 inches (e.g., about 0.133 inches in some arrangements). Other curvatures may be suitable in various embodiments. Table 2 illustrates example values for the radius of curvature R of various embodiments disclosed herein, when the impellers are in the deployed configuration.

Blade Thickness

In addition, the thickness of the blades **303** can be controlled in various implementations. In general, the thickness of the blades can range between about 0.005 inches and about 0.070 inches in some embodiments, for example in a range of about 0.01 inches to about 0.03 inches. It should be appreciated that the thickness can be any suitable thickness. The thickness of the blade **303** can affect how the blade **303** collapses against the hub **301** when compressed into the stored configuration and how the blade deforms when rotating in an operational configuration. For example, thin blades can deform more easily than thicker blades. Deformable blades can be advantageous when they elongate or deform by a suitable amount to increase flow rate, as explained above. However, as explained above, if the blade **303** deforms outward by an excessive amount, then the free end of the blade can disadvantageously contact the inner wall of the housing **202** when the impeller **300** rotates. On the other hand, it can be easier to fold thin blades against the hub **301** because a smaller force can sufficiently compress the blades **303**. Thus, it can be important in some arrangements to design a blade sufficiently stiff such that the blade **303** does not outwardly deform into the cannula or housing **202**, while still ensuring that the blade **303** is sufficiently flexible such that it can be easily compressed into the stored configuration and such that it deforms enough to achieve desired flow rates.

In some embodiments, the thickness of each blade can vary along the height h of the blade. For example, the blades can be thinner at the root of the blade **303**, e.g., near the hub **301**, and thicker at the free end of the blade **303**, e.g., near the wall W of the cannula housing **202**. As best seen in FIGS. **5**B-**5**C, for example, the leading edge of the blade can have a first thickness t_{1a} at the fixed end of the blade **303** and a second thickness t_{1b} at the free end of the blade **303**. Moreover, the trailing edge of the blade **303** can have a first thickness t_{2a} at the fixed end of the blade **303** and a second thickness t_{2b} at the free end of the blade **303**. Because the blades **303** are relatively thin near the hub **301**, the blades **303** can be easily folded into the stored configuration due to their increased flexibility near the hub **301**. Because the blades **303** are relatively thick at the free end (e.g., near the cannula wall W), the blades **303** may deform a suitable amount when the impeller rotates, reducing the risk that the blades **303** will contact or impact the wall W, which can accordingly reduce the risk of hemolysis, while deforming enough to achieve desirable flow rates. Moreover, in some embodiments, the thickness may vary continuously, such that there are no steps or discontinuities in the thickness of the blade. For example, even though the free end of the blades may be thicker in some embodiments, the thickness can continuously increase along the height of the blade.

As an example, the first thickness t_{1a} of the leading edge of the blade in FIGS. **5**A-**5**C can be in a range of about 0.016 inches to about 0.023 inches near the hub (e.g., about 0.02 inches at the hub in some arrangements), while the second thickness t_{1b} can be in a range of about 0.022 inches to about 0.028 inches at the free end (e.g., about 0.025 inches at the free end in some arrangements). Further, at the trailing edge of the blade of FIGS. **5**A-**5**C, the first thickness t_{2a} can be in a range of about 0.016 inches to about 0.023 inches near the hub (e.g., about 0.02 inches at the hub in some arrangements), and the second thickness t_{2b} can be in a range of about 0.03 inches to about 0.04 inches at the free end (e.g., about 0.035 inches at the free end in some arrangements). As another example, for the blade of FIGS. **10**A-**10**B, the first thickness t_{1a} of the leading edge can be in a range of about 0.022 inches to about 0.028 inches at the hub (e.g., about 0.025 inches near the hub in some arrangements), and the second thickness t_{1b} can be in a range of about 0.022 inches to about 0.028 inches at the free end (e.g., about 0.025 inches at the free end in some arrangements). At the trailing edge of the blade of FIGS. **10**A-**10**B, the first thickness t_{2a} can be in a range of about 0.016 inches to about 0.023 inches at the hub (e.g., about 0.02 inches in some arrangements), and the second thickness t_{2b} can be in a range of about 0.016 inches to about 0.023 inches at the free end (e.g., about 0.02 inches in some arrangements).

Fillets at Root of Blades

As explained above, a first fillet **311** can extend along the suction side **305** of each blade **303** at the proximal end of the blade **303** (e.g., at the root of the blade), and a second fillet **313** can extend along the pressure side **307** of each blade at the proximal end of the blade **303**. In general the first fillet **311** can have a larger radius than the second fillet **313**. The larger fillet **311** can be configured to apply a restoring force when the impeller **300** rotates in the operational configuration. As the impeller **300** rotates, the blades **303** may tend to deform in the distal direction in some situations (e.g., toward the distal portion of the hub **301**). By forming the fillet **311** at the suction side **305** of the blade, the curvature of the fillet can advantageously apply a restoring force to reduce the amount of deformation and to support the blade.

By contrast, the second fillet **313** formed on the pressure side **307** of the blade **303** can have a smaller radius than the first fillet **311**. The second fillet **313** can be configured to enhance the folding of the blade against the impeller when the blades **303** are urged into the stored configuration.

The radius r of each fillet can be any suitable value. For example, the radius r_1 of the first fillet **311** can range between about 0.006 inches and about 0.035 inches. The radius r_2 of the second fillet **313** can range between about 0.001 inches and about 0.010 inches. Other fillet radiuses may be suitable. For the implementation of FIGS. **5**A-**5**C, for example, the radius r_1 of the first fillet **311** can be about 0.015 inches, and the radius r_2 of the second fillet **313** can be about 0.005 inches. By contrast, for the impeller shown in FIGS. **10**A-**10**B, the first fillet **311** can have a radius r_1 of about 0.025 inches, and the second fillet **313** can have a radius r_2 of about 0.005 inches.

Wrapping Angle

In some implementations, the wrapping angle of each blade can be designed to improve pump performance and to enhance folding of the impeller into the stored configuration. In general, the blades can wrap around the hub at any suitable angle. It has been found that wrapping angles of between about 150 degrees and about 220 degrees can be suitable for folding the blades into the stored configuration. Further, wrapping angles of between about 180 degrees and about 200 degrees can be particularly suitable for folding the blades into the stored configuration.

Ramping Surface

Furthermore, as explained above, the trailing edge or the proximal end of each blade can include a ramp or chamfer formed at an angle θ with a plane perpendicular to the hub **301**, as illustrated above in, e.g., FIG. **5**C. FIG. **12** is a schematic, side cross-sectional view of an impeller **1200** having a hub **1201** and one or more blades **1203** disposed within a housing **1202**, similar to the housing **202** described above. As shown in FIG. **12**, the impeller **1200** is in the expanded or deployed configuration. For example, the impeller **1200** may be in the deployed configuration before packaging and shipping to a customer. Alternatively, the impeller **1200** may be in the deployed configuration after pumping blood in a patient and before withdrawal of the pump from the vasculature. As explained above, it can be desirable to compress the impeller **1200** into the stored configuration for inserting or withdrawing the operative device of the pump from the patient. To assist in compressing the impeller **1200** into the stored configuration, the blade(s) **1203** can include a ramp **1215** forming a ramp angle θ with a plane perpendicular to the hub **1201**.

An outer sheath or sleeve **1275** can be provided around an elongate body that extends between an operative device of the pump and the motor in the system. The sleeve **1275** can be used to deploy the impeller **1200** from the stored configuration to the deployed configuration and to compress the impeller **1200** from the deployed configuration back into the stored configuration. When compressing and storing the impeller **1200** and the housing **1202**, for example, a user, such as a clinician, can advance the sleeve **1275** in the +x-direction, as shown in FIG. **12**. When urged in the +x-direction, the sleeve **1275** can bear against a contact portion **1235** of the housing **1202**. The contact portion **1235** of the housing **1202** can in turn bear against the ramp **1215**. Advantageously, the ramp angle θ can be angled distally such that when the sheath or sleeve **1275** is urged over the impeller **1200** and housing **1202**, the contact portion **1235** can contact the angled or ramped edge of the blades to compress the blades against the hub. The ramp angle θ can be any suitable angle. For example, in some embodiments, the ramp angle θ can be between about 30 degrees and about 50 degrees. In the implementation of FIGS. **5**A-**5**C and **12**, for example, the chamfer or ramp angle θ of the ramp **1215** can be in a range of about 40 degrees to 50 degrees (e.g., about 45 degrees in some arrangements). In the embodiment of FIGS. **10**A-**10**B, the ramp angle θ of the trailing edge can be in a range of about 35 degrees to 45 degrees (e.g., about 40 degrees in some arrangements). Still other ramp angles θ may be suitable to assist in storing the impeller. In some embodiment, the ramp **1215** can comprise a solid, relatively stiff portion against which the housing **202** and sheath may be advanced.

Blade Height-to-Hub Diameter Ratio

In some embodiments, a ratio σ of blade height (h) to hub diameter (D) can be defined. As explained above, the hub **301** can have a first diameter D_1 at a distal end portion of the impeller **300** (e.g., near a leading edge of the blade(s) **303**) and a second diameter D_2 at a proximal end portion of the impeller **300** (e.g., near a trailing edge of the blade(s) **303**). As used herein, the ratio σ may be defined relative to a diameter D, which, in some embodiments, may correspond to the first diameter D_1 or the second diameter D_2, or to an average of D_1 and D_2. The blade height h may be identified relative to the deployed configuration in some embodiments. As shown in FIGS. **5**A-**11**, the height h may be defined by a maximum distance between the hub **301** and the free end of the blade(s) **303**.

The ratio σ may be relatively large compared to conventional impellers. For example, as explained herein, it can be advantageous to provide for an impeller **300** having a low profile suitable, for example, for percutaneous insertion into the patient's vascular system. One way to provide a low profile impeller **300** is to reduce the volume of impeller material that is compressed within the outer sheath, e.g., the sheath within which the impeller **300** is stored during percutaneous delivery and insertion. Impellers having relatively large blade height-to-hub diameter ratios σ may allow for such compact insertion, while maintaining high flow rates. For example, larger blade heights h can allow for the use of smaller hub diameters D, and the larger blade heights h are also capable of inducing high flow rates that are advantageous for catheter pump systems. For example, in some embodiments, the blade height-to-hub diameter ratio σ can be at least about 0.95, at least about 1, at least about 1.1, and/or at least about 1.2, in various arrangements. In some embodiments, for example, the ratio σ can be in a range of about 0.7 to about 1.45 in various embodiments. In particular, the ratio σ can be in a range of about 0.7 to about 1.1 in some embodiments (such as the embodiment of FIGS. **10**A-**10**B, for example). In addition, in some arrangements, the ratio σ can be in a range of about 0.75 to about 1. In some embodiments, the ratio σ can be in a range of about 0.9 to about 1.1.

Example Impeller Parameters

It should be appreciated that the values for the disclosed impeller parameters are illustrative only. Skilled artisans will appreciate that the blade parameters can vary according to the particular design situation. However, in particular embodiments, the blade parameters can include parameter values similar to those disclosed in Tables 1-2 below. Note that length dimensions are in inches and angles are in degrees.

TABLE 1

Figure Number	No. of Blades	D_1 (in.)	D_2 (in.)	h (in.)	t_{1a} (in.)	t_{1b} (in.)	t_{2a} (in.)	t_{2b} (in.)
5A-5F	2	0.081	0.125	0.0995	0.02	0.025	0.02	0.035
6	2	0.081	0.125	0.1	0.02	0.02	0.015	0.02
7	3	0.0844	0.125	0.1025	0.015	0.015	0.02	0.02
8	2	0.097	0.12	0.107	0.015	0.02	0.015	0.02
10A-10B	3	0.0836	0.125	0.107	0.025	0.025	0.02	0.02
11	2	0.0798	0.125	0.109	0.03	0.025	0.015	0.02

TABLE 2

Figure Number	β (deg)	Wrap Angle (deg)	θ (deg)	r_1 (in.)	r_2 (in.)	R (in.)
5A-5F	40	210	45	0.015	0.005	0.12
6	40	210	45	0.015	0.005	0.07
7	40	270	46	0.015	0.005	0.133
8	40	200	40	0.015	0.005	0.12
10A-10B	40	220	40	0.025	0.005	0.133
11	30	210	35	0.015	0.005	0.09

One will appreciate from the description herein that the configuration of the blades may be modified depending on the application. For example, the angle of attack of the blades may be modified to provide for mixed flow, axial flow, or a combination thereof. The exemplary blades of the illustrated figures are dimensioned and configured to improve axial flow and reduce hemolysis risk. The exemplary blades are shaped and dimensioned to achieve the desired pressure head and flow rate. In addition, the single blade row design is thought to reduce the turbulent flow between blade rows with other designs and thus may reduce hemolysis.

Flow Modifying Structures

The impeller designs discussed herein are fully capable of providing flows to meet patient needs, as discussed below. However, pump performance can be even further improved by incorporating flow modifying structures downstream of the impeller, e.g., a stator or other structure providing flow directing or modifying structure (e.g. blades) in the flow stream. The flow modifying structures advantageously aligns a rotational, complex flow field generated by the high speed rotation of any of the impellers described herein into a more uniform and laminar flow, in some cases a substantially laminar. This alignment of the flow converts rotational kinetic energy near the blades into pressure. Absent the flow modifying structures, the energy in the complex field would be dissipated and lost. This alignment of the flow reduces losses due to the disorganized nature of the flow exiting an impeller.

FIGS. **15-19** show details of a catheter assembly **400** and an exemplary flow modifying structure **402** disposed in a distal portion of the assembly **400** downstream from the impeller. The flow modifying structure can be a stator or stator assembly. The flow modifying structure **402** can include a blade body **404** having one or a plurality of, e.g., three, blades **408** extending outwardly from a central body **412**. In the exemplary embodiment, flow modifying structure **402** is a stator having a plurality of blades **408** configured to align or straighten flow from the impeller in an axial direction. FIG. **19** shows that central body **412** is hollow, enabling it to be mounted on a structure of the catheter assembly **400**. The blade body **404** is at a downstream location of the impeller **300**. In a percutaneous left ventricle application, the blade body **404** is disposed proximal of the impeller **300**. In a percutaneous right ventricle application, the blade body **404** is located distal of the impeller **300**. In a transapical approach to aid the left ventricle, which might be provided through ports in the chest wall or via thoracotomy or mini-thoracotomy, the stator blade body **404** is disposed distal of the impeller **300**. It should be appreciated that the flow directing structure **402** described herein may be implemented with any of the impellers **300-300**J disclosed herein to improve pump performance.

The flow modifying structure **402** can be formed as a unitary body with collapsible blades **408**. The exemplary blades **408** are collapsible and resiliently expandable, e.g., by releasing stored strain energy. In some embodiments, at least the blades **408** are actuatable to an expanded state and do not require storing and releasing stored strain energy. For example, the blades **408** can be inflatable or actuated by some mechanical means such as a pull wire to be enlarged from a low profile delivery state to an operational state.

The blades **408** are configured to act on the fluid flow generated by the impeller **300** to provide a more clinically useful flow field (e.g., laminar) downstream of the flow modifying structure **402**. The blades **408** can improve efficiency by changing the flow field from the impeller into a more clinically useful flow field as it is output from the catheter pump **10**. The blades **408** transform complex, mostly radial flow vectors generated by the impeller **300** into more uniform axial flow vectors. In some cases, the blades **408** are configured to reduce other inefficiencies of the flow generated by the impeller **300**, e.g., minimize turbulent flow, flow eddies, etc. Removing radial and/or circumferential flow vectors of the flow can be achieved with blades that are oriented in an opposite direction to the orientation of the blades of the impeller **300**, for example, clockwise versus counterclockwise oriented blade surface. For example, the wrapping direction of the blades of FIG. **10**A is the opposite of that of the blades in FIG. **18**.

While the blades **408** act on the flow generated by the impeller **300**, the fluids also act on the flow modifying structure **402**. For example, the blade body **404** experiences a torque generated by the interaction of the blades **408** with the blood as it flows past the assembly **402**. A mechanical interface is provided between the central body **412** and a distal portion of the catheter assembly **400**. For example, the central body **412** of the flow modifying structure **402** can be mounted, on a housing that also supports rotation of the impeller **300**. Preferably the interface is self-tightening, as discussed in U.S. patent application Ser. No. 13/801,833, filed Mar. 13, 2013, entitled "SHEATH SYSTEM FOR CATHETER PUMP," which is incorporated by reference herein in its entirety.

An important feature of the catheter assembly **400** is defining a small gap G between the flow modifying structure **402** and the impeller **300**. The gap G is provided to accommodate relative motion between the impeller **300** and the flow modifying structure **402**. The flow modifying structure **402** can be held in a constant rotational position, while the impeller **300** rotates at a high rate. The gap G helps to reduce friction between and wear of the impeller **300** and the central body **412** of the flow modifying structure **402**. The gap G should not be too large, however, to provide appropriate flow between the blades of the impeller **300** and the stator blades **408**. A large gap could provide a high pressure drop (i.e. hydraulic efficiency loss), which his disadvantageous. As discussed more below, the blades **408** modify the flow characteristics of blood between the impeller **300** and an outlet of the cannula **202**.

FIGS. **15-19** illustrate more features of the flow modifying structure **402**. The blades **408** preferably extend along a distal length of the blade body **404**. The blades **408** can extend from a leading edge **420** to a trailing edge **424** between a blade root **428** and a distal edge **432**. The leading edge **420** can be any suitable shape to minimize inefficient transfer flow from the impeller **300**. For example, the blade **408** can have a convex expanse **436** disposed between the leading and trailing edges **420**, **424**.

In FIG. **17** the convex expanse **436** is formed to follow a curve profile of the distal edge **432** of the blade **408**. The convex expanse **436** has a complex curved shape including a distal portion that has relatively high curvature and a proximal portion that has less curvature. The relative curvatures can be seen in comparing the leading edge portion in of blade **408**A and the curvature of the trailing edge portion of the blade **408**B in FIG. **17**. In this embodiment, the blades **408**A, **408**B are identical but are mounted at spaced apart locations, e.g., 120 degrees from each other. Though the structure is not easily rendered in a two dimensional format, the portion A at the leading edge **420** has a higher curvature than the portion B disposed between the leading edge **420** and the trailing edges **424**.

A gradual reduction in the degree of curvature is preferred to act on the blood directed proximally from the impeller **300**. The flow generated by the impeller **300** can be characterized as a complex flow field. A gradual change in the angle of the blades **408** will efficiently transform the complex flow field into a more unified, ordered field, e.g., generally axially directed and more laminar. The blades **408** reduce the rotational inertia of the flow that tends to carry the flow circumferentially and radially outwardly to direct the flow proximally, while minimizing turbulence and other inefficient flow regimes. A tangent to the curvature of the distal edge **432** is indicative of the direction in which the blade **408** will tend to direct the flow interacting with the blade **408**. In the region A, a tangent to the curve of the distal edge **432** (or the expanse **436** or **440**) can be disposed at an angle α to a line parallel to the longitudinal axis of the central body **412**. The angle α is shown on FIG. **18**. The angle α is selected to allow the blood flowing off of the impeller to enter the space defined between the expanse **436** and the expanse **440** on adjacent blades (see FIG. **17**). The angle α can be less than about 60 degrees in one embodiment, and less than about 50 degrees in another embodiment, in some embodiments less than about 45 degrees. The angle α can be between about 30 degrees and about 70 degrees, and in some cases between about 40 and about 60 degrees.

In the region B, a tangent to the curve of the distal edge **432** (or the expanse **436** or **440**) is at a relatively low angle to a preferred flow direction. In one embodiment, it is preferred that the flow within the channel defined between the expanse **436** and the expanse **440** of adjacent blades approach a direction that is more axial than the flow in the area of the impeller **300** and more axial than downstream of the impeller **300** where the stator assembly **402** not present. In some cases, the flow in the channel defined between the expanse **436** and the expanse **440** of adjacent blades approaches a direction generally parallel to the longitudinal axis of the catheter assembly **400**. The angle of the structures of the blades in the region B, e.g., the tangent to the curvature at the distal edge **432**, is between about 20 and about 50 degree, and in some cases between about 30 and about 40 degrees and in some cases between 35 and about 45 degrees.

In some embodiments, the angle of trailing edge features relative to the desired direction of flow is a feature that can be advantageously controlled. For example, the angle β can be provided between the blade root **428** in the region C and an axis parallel to the longitudinal axis of the central body **412** of the stator assembly **402**. The angle β is between about zero and about 30 degrees, and in some cases is between about 5 and 20 degrees, and in other cases is no more than about 20 degrees, and can be less than about 10 degrees.

FIG. **18** shows that the angles α and β define a flow channel between the expanse **436** of the blade **408**A and the expanse **440** of the blade **408**B. The expanse **436** can include one side of the blade **408**A and the expanse can include one side of the blade **408**B. A leading edge portion of the channel defined in this manner has relatively high curvature along the sidewalls. A trailing edge portion of the channel defined in this manner has relatively low curvature along the sidewalls. The change in curvature helps shape the average flow direction of the flow of blood coming from the impeller **300** and exiting the channels in the stator assembly **402**.

As discussed herein, the catheter pumps herein are configured for low profile delivery but the impeller **300** is expandable to provide for superior flow performance. The blades **408** of the flow modifying structure **402** closely match the profile of the blades of the impeller **312**. For example, in the deployed state, the blades of the impeller **312** extend a distance from a blade root by a distance that is about the same distance as is measured from the blade root **428** to the blade distal end **432**. Because the blades **408** are to be delivered through the same profile as the impeller, the blades **408** are also to be collapsible in some embodiments.

Various features may be provided to facilitate deployment and collapse of the flow modifying structure **402**. Fillets **411**, **413** similar to those hereinbefore described in connection with the impeller **300** can be provided to facilitate stability of the stator blades **408** in operation of the pump and the collapse of the stator blades. The fillets **411**, **413** preferably have a first portion disposed on the central body **412** and a second portion disposed at the junction of the blade root **428** with the convex expanse **436** and the concave expanse **440**. In one stator collapse strategy, the blades are configured to fold distally and into the direction of curvature of the distal edge **432**. In other words, the expanse **436** is moved toward the central body **412** upon advancement of a distal end of the sheath assembly **88** discussed above. More particularly, relative axial motion of the distal end of the sheath assembly **88** over the trailing edge **424** of the blades **408** causes bending around the fillet **411** disposed between the expanse **436** and the central body **412**. The bending is initially at the trailing edge **424** and progresses toward the leading edge **420** until the expanse **436** of each blade is folded down onto a corresponding portion on of the central body **412** between the expanse **436** and an expanse **440** of an adjacent blade.

Another feature that facilitates collapse is the configuration of the trailing edge **424**. The trailing edge **424** is disposed at an angle θ relative to an axis parallel to the longitudinal axis of the central body **412** of the stator assembly **402**. The angle θ may be any of those discussed above in connection with the ramped surface of the impellers **300**. The angle θ can be in a range of about zero to about 70 degrees. In some embodiments, the angle θ can be in a range of about 20 to about 60 degrees, in other embodiments, the angle θ can be between about 30 and 55 degrees. In other embodiments, the angle θ can be less than about 60 degrees.

A trailing edge cylindrical portion **454** is disposed between the trailing edges of the fillets **411**, **413** and the proximal end of the central body of the stator assembly **402**. The cylindrical portion **454** spaces the trailing edges **424** and the fillets **411**, **413** from the boundary between the central body **412** and more proximal portions of the catheter assembly **400**. This allows blood to transition from three separate flows in the region of the blades to a single unified flow field between the proximal most portion of the trailing edge **424** and the transition from the cylindrical body **412** to another more proximal structure. By separating these transitions axially the flow is maintained more organized, e.g., is less likely to become more turbulent due to complex circumferential, radial, and axial boundaries.

Improving Patient Outcomes

As explained herein, it can be desirable to pump blood at relatively high flow rates in order to provide adequate cardiac assistance to the patient and to improve patient outcomes. It should be appreciated that, typically, higher impeller rotational speeds may increase flow rates because the impeller is driven at a higher speed. However, one potential disadvantage of high impeller speeds is that blood passing across or over the rotating components (e.g., the impeller and/or impeller shaft or hub) may be damaged by the shearing forces imparted by the relatively rotating components. Accordingly, it is generally desirable to increase flow rates for given rotational impeller speeds.

The various features disclosed herein can enable a skilled artisan to provide an impeller capable of increasing or maintaining flow rates at lower rotational impeller speeds. These improvements are not realized by mere increases in rotational speed or optimization of the impeller design. Rather, the improvements lead to a significant shift in the performance factor of the impeller, which reflect structural advantages of the disclosed impellers.

FIG. **13** is a chart plotting flow rate versus motor speed for the impellers illustrated in FIGS. **10A-10B** and **9E**. Note that, in the illustrated chart of FIG. **13**, however, that the impeller speed is the same as the motor speed, e.g., no clutch is used between the motor and impeller shaft. Thus, the plotted values in FIG. **13** represent flow rates at various impeller rotational speeds. The flow rates were measured by running the impellers on a closed mock loop on the bench with a blood analog. The back pressure (e.g., head pressure or change in pressure across the pump) was at about 62 mmHg for the impellers **300**D, **300**J of FIGS. **10A-10B** and **9**E, respectively. The results on the bench top mirror those achieved in animal investigations.

As shown in FIG. **13**, the impeller **300**D provides for higher flow rates at lower speeds than the impeller **300**J of, e.g., FIG. **9**E. For example, the impeller **300**J of FIG. **9**E may be capable of pumping blood at flow rates in a range of about 4.5 liters per minute (LPM) to about 5.5 LPM when the impeller is operating at speeds in a range of about 25,000 revolutions per minute (RPMs) to about 28,000 RPMs. For example, the impeller of FIG. **9**E may be capable of pumping blood at a flow rate of about 5.5 LPM when the impeller is operating at speeds in a range of about 26,000 RPMs to about 28,000 RPMs.

In FIG. **13**, the flow rate of the impeller **300**J can be plotted along a line X, in which flow rate increases with impeller rotational speed, which is the same as motor speed in FIG. **13**. With prior designs, increased flow rate can only be achieved by increasing the rotational speed to move along the line X. Prior, it was expected that optimization of the impeller design can only realize minor improvements to the flow versus RPM curve. At best, the impeller could be configured to achieve minor improvements at the extremes or with a slight change in the curve X, such that the line or curve X might have a slightly higher slope.

For example, with the impeller **300**J of FIG. **9**E, the impeller speed at data point X**1** is about 21,000 RPM, which yields a flow rate of about 1.9 LPM. With the impeller **300**J of FIG. **9**E, flow rate can indeed be increased to above about 5 LPM, e.g., about 5.4 LPM, at data point X**2**, but the impeller rotational speed required to achieve such improvements in flow rate also increases to about 27,000 RPM. Thus, even though the impeller **300**J of FIG. **9**E can achieve relatively high flow rates, the high flow rates come at the expense of a higher impeller speed, which, as explained above, can cause hemolysis and undesirable patient outcomes.

By contrast, the impeller **300**D of FIGS. **10A-10B** achieves significant and unexpected performance improvements. The exemplary impeller has been found to achieve dramatically higher flow rates at all rotational speeds. For example, the impeller **300**D of FIGS. **10A-10B** can achieve flow rates above 4.25 LPM, indeed even above about 5 LPM, while maintaining a low impeller speed of less than about 21,000 RPM (which, by contrast, induced a flow rate of only about 1.9 LPM in the impeller **300**J of FIG. **9**E). Thus, the design of the impeller **300**D of FIGS. **10A-10B** can advantageously achieve structural advantages relative to the impeller **300**J. Indeed, the curve labeled Y in FIG. **13** illustrates the dramatic shift of the flow rate curve to the left in FIG. **13**, which indicates significantly increased flow rates at lower impeller speeds relative to prior impeller designs. The exemplary impeller has also been found to have a dramatically improved head pressure versus flow rate (HQ) performance versus conventional designs.

The exemplary impeller **300**D of FIGS. **10A-10B** has been found to be capable of pumping blood at flow rates in a range of about 4.5 LPM to about 5.5 LPM when the impeller is operating at speeds in a range of about 19,000 RPM to about 21,000 RPM, e.g., when the impeller is operating at speeds less than about 21,000 RPMs. For instance, the impeller **300**D of FIGS. **10A-10B** may be capable of pumping blood at a flow rate of about 5.5 LPM when the impeller is operating at speeds in a range of about 20,000 RPMs to about 21,000 RPMs. Further, the impeller **300**D of FIGS. **10A-10B** may be capable of pumping blood at a flow rate of about 5 LPM when the impeller is rotating at speeds in a range of about 19,000 RPMs to about 21,000

RPMs. In some arrangements, when the impeller is operating at a speed of about 19,500 RPMs, the flow rate may be in a range of about 4.5 LPM to about 5.1 LPM.

Further, the impeller **300**D of FIGS. **10**A-**10**B is capable of pumping blood at a flow rate of at least about 3.5 LPM, and/or at least about 4.25 LPM, when the impeller is operating at speeds less than about 21,000 RPMs. For example, the impeller **300**D is capable of pumping blood at a flow rate of at least 4.25 LPM when the impeller is operating at speeds in a range of about 18,500 RPM to about 22,000 RPM, for example in a range of about 18,500 RPM to about 21,000 RPM. For example, the impeller **300**D is capable of pumping blood at a flow rate in a range of about 4.25 LPM to about 5.5 LPM when the impeller is operating at speeds in a range of about 18,500 RPM to about 21,000 RPM. The flow rates achieved at these impeller speeds may be achieved at a back pressure or head pressure of at least 60 mmHg, e.g., at about 62 mmHg in some embodiments. Further the impeller **300**D capable of achieving the performance of FIG. **13** may also be sized and shaped to be inserted into a vascular system of a patient through a percutaneous access site having a catheter size less than about 21 FR.

The impeller **300**D of FIGS. **10**A-**10**B may therefore provide a dramatic and unexpected jump in flow rates relative to the impeller **300**J of FIG. **9**E. The shift in performance allows the impeller **300**D to achieve a maximum flow rate far exceeding conventional and/or previous designs and at a rotational speed a mere fraction of that for which conventional pumps are designs. Thus, FIG. **13** illustrates that the impeller **300**D of FIGS. **10**A-**10**B yields improved patient outcomes and reduced hemolysis relative to the impeller **300**J of FIG. **9**E.

FIG. **14** is a chart plotting flow rate versus motor speed (e.g., impeller speed) for an impeller similar to or the same as the impeller **300**D of FIGS. **10**A-**10**B, as compared to various conventional microaxial, rotary pumps. In particular, Curve A in FIG. **14** plots flow rate versus motor speed (again, the same as impeller speed in FIG. **14**) for the impeller associated with Curve A, according to test data taken using a blood analog at about 62 mmHG back pressure.

Curve B plots approximate flow rate versus motor speed for the heart pump disclosed in the article of J. Stolinski, C. Rosenbaum, Willem Flameng, and Bart Meyns, "The heart-pump interaction: effects of a microaxial blood pump," *International Journal of Artificial Organs*, vol: 25 issue: 11 pages: 1082-8, 2002, which is incorporated by reference herein in its entirety and for all purposes. The test data from Curve B was obtained under test conditions having a back pressure of about 60 mmHg.

Curve C plots approximate flow rate versus motor speed for the heart pump disclosed in the article of David M. Weber, Daniel H. Raess, Jose P. S. Henriques, and Thorsten Siess, "Principles of Impella Cardiac Support," *Supplement to Cardiac Interventions Today,* August/September 2009, which is incorporated by reference herein in its entirety and for all purposes. The test data from Curve C was obtained under test conditions having a back pressure of about 60 mmHg.

Data point D plots approximate flow rate versus motor speed for the heart pump disclosed in Federal and Drug Administration 510(k) Summary for Predicate Device IMPELLA 2.5 (K112892), prepared on Sep. 5, 2012, which is incorporated by reference herein in its entirety and for all purposes. In particular, for data point D, the disclosed pump was capable of mean flow rates of up to 3.3 LPM at pump speeds of 46,000 RPM at a 60 mmHg differential pressure.

As shown in FIG. **14**, the disclosed impeller associated with Curve A can achieve higher flow rate at all impeller speeds relative to the pumps of Curves B, C, and D. The data reflected in FIG. **14** was not all collected by precisely the same methodology in a head-to-head fashion, as noted above. However, the data are shown on a single chart for the convenience of the reader and are still compelling. For example, as discussed above, the back-pressure conditions under which the Curve A data was collected (for impellers disclosed herein) was higher than that collected for the other devices. Were this test condition the same, the results would be all the more impressive. Indeed, data points A**1** and A**2** of Curve A, for example, provide higher flow rates at significantly lower impeller rotation rates than any of the data points along Curves B-C or at point D (e.g., data points B**1**, B**2**, B**3**, C**1**, C**2**). In addition, as shown in FIG. **14**, the impeller of Curve A can achieve flow rates of about 7 LPM at impeller speeds of only about 25,000 RPM, as shown by Curve A. By contrast, curves B-C and data point D do not even indicate that the conventional axial pumps can achieve 7 LPM flow rates at any impeller speed. Thus, the impeller associated with Curve A of FIG. **14** can achieve higher flow rates at lower rotational speeds than conventional catheter pumps, such as microaxial, rotary pumps, (e.g., Curves B-C and data point D of FIG. **14**). In addition, the disclosed impellers can also be configured to achieve higher maximum flow rates than conventional pumps.

In addition, the data of Curves B-C and data point D of FIG. **14** represent another constraint on the design of conventional rotary pumps. For example, the pump plotted on Curve B has a diameter corresponding to a catheter size of about 21 FR. Flow rates may be increased for the pump of Curve B by increasing the diameter of the pump. However, further increases in pump diameter for the device of Curve B may disadvantageously increase the pump diameter requiring more invasive techniques to position the pump. Thus, increasing flow rate by increasing pump diameter may not be a feasible or desirable alternative for catheter pumps, and/or it may not be desirable for acute heart failure where fast implantation is critically important.

By contrast, as shown in Curve A of FIG. **14**, the impeller (e.g., which can be the same as or similar to the impeller **300**D disclosed herein) advantageously has an insertion diameter corresponding to a catheter size of less than about 13 FR, e.g., about 12.5 FR in some embodiments, which can enable minimally-invasive insertion techniques, even at higher flow rates and lower impeller rotation rates. Thus, the disclosed impeller of Curve A can provide higher flow rates at lower impeller speeds than conventional microaxial, rotary pumps, and can maintain lower insertion diameters for minimally invasive techniques.

Indeed, the impeller of Curve A may be configured to be inserted into vascular system of a patient through a percutaneous access site having a size less than 21 FR. The impeller of Curve A (e.g., which may be similar to or the same as impeller **300**D) may include one or more blades in a single row. In some embodiments, the impeller can be configured to pump blood through at least a portion of the vascular system at a flow rate of at least about 2.0 liters per minute when the impeller is rotated at a speed less than about 21,000 revolutions per minute. In some embodiments, the blades are expandable.

FIG. **14**A shows a performance curve for several catheter pumps to illustrate the capability of a catheter pump that includes the catheter assembly **400**. Catheter pump performance can be characterized by the relationship between the pump's pressure differential H and flow rate Q at a given rotor speed S. This relationship can be represented by a map or graph, as shown in FIG. **14**A. In FIG. **14**A, the pressure differential H is represented by the Y axis and the flow rate Q by the X axis. For a given pump speed, the relationship between the pressure differential H and the flow rate Q is represented by an H-Q curve on the graph. As a result, a map of the continuous flow pump includes a family of H-Q curves, each curve representing a relationship between the pressure differential H and the flow rate Q for every different pump speed S.

The family of H-Q curves in FIG. **14**A represents the H-Q characteristics of the pump **10** with the catheter assembly **400** and several other pumps. The native H-Q characteristics, including the shape, steepness (slope) and location of individual H-Q curves, is generally unique to the particular hydraulic design of pump and varies from one pump to another. As used herein, "H-Q" is an abbreviation for "pressure-flow." The phrases "H-Q curve" and "pressure-flow curve" have the same meaning and are used interchangeably. The phrases "H-Q characteristics" and "pressure-flow characteristics" have the same meaning and are used interchangeably.

FIG. **14**A is a map of an axial flow pump generated by test data as would be understood by one of skill in the art. The term "map" refers to mapping of relationships between pressure differential H, flow rate Q and rotor speed S.

In FIG. **14**A, the actual or expected performance of each of four distinct pumps is illustrated. A first pump is illustrated by a consistent dashed line, and labeled "Conventional Pump C". This line represents the pump performance of an Impella® 2.5 pump based on published data in "Principles of Impella Cardiac Support", referenced above. A second pump, labeled "Convention Pump D" is illustrated by a triangle at a single point. This data is included in a 510(k) submission to the United Stated FDA for Impella® 2.5 Plus, discussed above. A third pump ("A-**1**") is illustrated by a series of solid lines, and corresponds to a pump having an expandable impeller similar to those discussed herein. A pump including flow modifying structures similar to the flow direction structures **402** was fabricated and tested. The pump test showed about a 15 percent improvement over the performance of a similar pump without the flow modifying structure. It is anticipated that further embodiments will yield a 10-15% increase in head pressure compared to a comparable design without the flow modifying structures. The expected performance of the fourth pump including the catheter assembly **400** ("A-**2**") is illustrated in line with repeating dash and two dots.

As can be seen, for the first three curves where data was collected or retrieved from the literature by the assignee of this application, the pump A-**1** has far superior performance overall. The family of curves for the pump A-**1** demonstrates higher maximum flow rates than either Convention Pump C or D. Comparable or larger flow rates are achieved with impeller speeds that are significantly less than that of the other pumps for which data was collected or available. For example, for Conventional Pump D the motor speed required to obtain the flow rate as charted was 45,000 RPM whereas the pump A-**1** achieved comparable flows at only 19,000 RPM. As discussed herein, these lower impeller speeds for pump A-**1** are expected to provide much superior patient outcomes at least because hemolysis and other potentially deleterious blood interactions at the impeller will be dramatically reduced.

The pump A-**2** is expected to provide even higher flow performance than that of pump A-**1**. The chart illustrates the expected H-Q performance at 22,000 RPM for a pump including the catheter assembly **400**. The improved performance relates to a transformation of the flow field coming off of the impeller **300** into a more laminar state from a more complex flow field. The transformation converts kinetic energy associated with a rotational component of the flow into additional pressure, enhancing the performance. This line suggests a number of possible improvements that could be implemented in the operation or configuration of the pump A-**2**. For example, if the impeller diameter is the same in the pump A-**2** as in the pump A-**1**, the pump A-**2** could operate at a lower RPM while providing the same output (flow rate) as that of the pump A-**1**. Or, if the pump A-**2** is operated at the same speed as the pump A-**1**, the output could be higher with the pump A-**2** for comparable amount of hemolysis.

A third advantage in view of the performance of the pump A-**2** is that a smaller device could be made that would achieve the same output as the pump A-**1** at the same impeller speed. For example, the device could be reduced in size to enable it to be placed in smaller blood vessels or through smaller sheaths such as the femoral artery or smaller vessels in the arterial system. A significant advantage of reducing the size of the pump **10** is that there will be less blockage of flow in the femoral (or similar sized) artery to downstream tissue fed by the vasculature. Blockage can lead to ischemia of the tissue. Avoiding ischemia makes the pump **10** more biocompatible generally and may enable the pump to be used for longer durations or with more patients.

Although the inventions herein have been described with reference to particular embodiments, it is to be understood that these embodiments are merely illustrative of the principles and applications of the present inventions. It is therefore to be understood that numerous modifications can be made to the illustrative embodiments and that other arrangements can be devised without departing from the spirit and scope of the present inventions as defined by the appended claims. Thus, it is intended that the present application cover the modifications and variations of these embodiments and their equivalents.

What is claimed is:

1. A catheter pump assembly, comprising:
a proximal portion;
a distal portion;
a catheter body having a lumen extending along a longitudinal axis between the proximal and distal portions;
an impeller disposed at the distal portion, the impeller including a blade attached to a hub, wherein the impeller is configured to rotate about an axis; and
a flow modifying structure disposed downstream of the impeller, the flow modifying structure having a plurality of substantially similar blades, wherein each blade includes a plurality of curvatures that combine to discharge a fluid in a generally axial direction from a downstream end of the flow modifying structure; and
wherein the flow modifying structure is collapsible from a deployed configuration to a collapsed configuration.

2. The catheter pump assembly of claim **1**, wherein each blade includes a curved distal edge and an upstream portion, wherein a line tangent to the distal edge and a line parallel to the axis define a first angle of curvature therebetween.

3. The catheter pump assembly of claim **2**, wherein the first angle of curvature is within a range of approximately 40 degrees and 60 degrees.

4. The catheter pump assembly of claim 2, wherein the first angle of curvature is less than 40 degrees.

5. The catheter pump assembly of claim 2, wherein each blade includes an intermediate portion downstream from the upstream portion, wherein a line tangent to the distal edge and a line parallel to the axis define a second angle of curvature therebetween.

6. The catheter pump assembly of claim 5, wherein the second angle of curvature is within a range of approximately 30 degrees and 40 degrees.

7. The catheter pump assembly of claim 5, wherein the second angle of curvature is within a range of approximately 35 degrees and 45 degrees.

8. The catheter pump assembly of claim 5, wherein each blade includes a root and a downstream portion downstream from the intermediate portion, wherein the blade root and a line parallel to the axis define a third angle of curvature therebetween.

9. The catheter pump assembly of claim 8, wherein the third angle of curvature is less than both the first angle of curvature and the second angle of curvature.

10. The catheter pump assembly of claim 8, wherein the third angle of curvature is within a range of approximately 5 degrees and 20 degrees.

11. The catheter pump assembly of claim 8, wherein the third angle of curvature is less than 20 degrees.

12. The catheter pump assembly of claim 1, wherein the impeller blade is wrapped around the hub in one of a clockwise or counter-clockwise direction, and the plurality of flow modifying structure blades are wrapped around a central body in the remaining one of the clockwise or counter-clockwise direction.

13. The catheter pump assembly of claim 1, wherein the flow modifying structure is collapsible to a smaller diameter for percutaneous insertion.

14. The catheter pump assembly of claim 1, wherein the flow modifying structure is proximal the impeller.

15. A flow modifying structure for use in a catheter pump assembly having an impeller configured to rotate about an axis, the flow modifying structure comprising:

a hub; and

a plurality of substantially similar blades, wherein the blades of the flow modifying structure are configured to transform radial flow vectors generated by the impeller into more uniform axial flow vectors; and

wherein the flow modifying structure is collapsible from a deployed configuration to a collapsed configuration to facilitate percutaneous insertion.

16. The flow modifying structure of claim 15, wherein each blade includes a curved distal edge and an upstream portion, wherein a line tangent to the distal edge and a line parallel to the axis define a first angle of curvature therebetween, wherein the first angle of curvature is within a range of approximately 30 degrees and 70 degrees.

17. The flow modifying structure of claim 16, wherein the first angle of curvature is less than 50 degrees.

18. The flow modifying structure of claim 16, wherein each blade includes an intermediate portion downstream from the upstream portion, wherein a line tangent to the distal edge and a line parallel to the axis define a second angle of curvature therebetween, wherein the second angle of curvature is within a range of approximately 20 degrees and 50 degrees.

19. The flow modifying structure of claim 18, wherein each blade includes a root and a downstream portion downstream from the intermediate portion, wherein the blade root and a line parallel to the axis define a third angle of curvature therebetween, wherein the third angle of curvature is within a range of approximately 0 degrees and 30 degrees.

20. The flow modifying structure of claim 19, wherein the third angle of curvature is less than 10 degrees.

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